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IMMUNOSUPPRESSIVE DRUG THERAPY ACT OF 1986

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-NINTH CONGRESS

SECOND SESSION

ON

S. 2536

TO PROVIDE FOR BLOCK GRANTS TO STATES TO PAY THE COSTS OF IMMUNOSUPPRESSIVE DRUGS FOR ORGAN TRANSPLANT PATIENTS

JUNE 11, 1986

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IMMUNOSUPPRESSIVE DRUG THERAPY ACT OF 1986

WEDNESDAY, JUNE 11, 1986

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 10:05 a.m., in room SD-430, Dirksen Senate Office Building, Senator Orrin Hatch (chairman) presiding.

Present: Senators Hatch, Kennedy, Grassley, Pell, Dodd, Simon, and Nickles.

Also present: Senator Albert Gore, Jr.

OPENING STATEMENT OF SENATOR HATCH

The CHAIRMAN. We are happy to call the committee to order.

Ladies and gentlemen, today, we will have the privilege to hear a great success story of American medicine. In 1984, approximately 32,000 human organ and tissue transplant operations were performed in this country—6,900 kidney, 24,000 cornea, 350 liver, 300 heart, 40 heart-lung, and 90 pancreas transplants were performed. And the number of these procedures performed was up 33 percent from the number performed just 2 years ago.

These procedures saved the lives, or greatly improved the health or restored vision for thousands of our fellow citizens.

And just as important, along with the explosion in the number of transplants has come a dramatic improvement in the success rate. Over the last 5 years, survival rates have more than doubled for most transplant patients.

These advances have not just happened by accident. They are the direct result of the hard work and the dedication of many of our scientists in this country, especially research scientists, much of whose work was funded by the Federal Government, and of splendid and far-reaching research by the American pharmaceutical industry.

These gains, while spectacular, have not come cheaply. The average cost of a kidney transplant is $30,000. The average for heart transplants is $85,000. And it is not unusual for liver transplants to cost more than $130,000.

In 1984, we spent almost $300 million on these three types of transplants alone. But as staggering as these numbers are, they may just be the tip of the iceberg, because it has been estimated that fewer than half of all eligible patients receive transplants due to a shortage of available organs.

To give you just a small idea of the potential cost of this new technology, it has also been estimated that we could be performing from 1,000 to 1,400 heart transplants a year.

If this objective is met, we would be spending over $1 billion a year just for heart transplants. And that estimate does not include the cost of followup care.

On the other hand, all those mind-boggling statistics and numbers should not cause us to lose sight of the truly important side of this issue.

Today, we will hear from the parents of a precious little 1-year-old angel of a girl who would not be alive today but for a liver transplant. And when you see a special little girl like Keilie, it is hard to think about this issue in terms of dollars and cents. You just have to reach out and love her and all the transplants patients like her. Truly, this new technology gives the gift of life.

The tremendous costs and the tremendous potential of transplantation, and the tremendous responsibility for little ones like Keilie, make this a very challenging issue for those of us charged with the oversight of Government programs in this area.

In fact, although decades of work went into getting us where we are today, in many ways the easy work is behind us because we are now faced with a number of very disquieting questions.

How, for example, will we increase the supply of organs available for transplant? Who will receive these organs? Will we allow all foreign citizens to receive transplants in this country who need them? How will we pay the enormous costs of these procedures? Who will we allow to perform these procedures? Which procedures will we approve? What are the legal ramifications? You can go on and on.

I do not have answers to these questions, but I have definite ideas about a direction that I do not want to see us go in regarding how we should pay for them.

Some have proposed that Medicare should pay for all transplants, but we all know that that is not what Medicare was intended for.

Medicare is intended to help pay for the health needs of our older citizens, and very few older people require organ transplants. The Medicare Trust Fund, although healthier than it was before prospective payment for hospital care was implemented in 1984, is still under strain, and the elderly are forced to pay more and more of the cost of their health care.

Any plan which may take hundreds of millions or even billions of dollars intended for them and transfers it to others needing costly transplant surgery, even with the best of intentions is, in my opinion, simply not the best solution to paying for this new technology.

For transplant patients who are not eligible for Medicare, we simply have to find another way.

As we struggled with these issues in 1984, we passed legislation establishing the Task Force on Organ Procurement and Transplantation. The full results of this bill will be released soon. This report should help answer some of the difficult questions that I have raised and many that I did not raise here today.

In addition, I understand the President is working on a reassessment of the administration position on organ transplantation, and I look forward as well to their report—and, I might add, as well as the one we will receive from the task force on the progress they have made and where we should go from here.

Unfortunately, because the transplant issue raises so many difficult questions, because it involves questions of life and death for little ones like Keilie, we must avoid turning this into a football for personal or political gain.

We, I think, have been able to avoid that in this committee. Senator Kennedy and I have had very different views on many issues, but when it comes to our Nation's health, we always seem to find some common ground. A good example of this is the immunosuppressive drug bill which we have just introduced together.

On this legislation, as we have in the past, Senator Kennedy and I got together and worked out our differences, and I want to compliment him for his willingness to work with me for the good of others. He is, I think, one of the paramount leaders in this field for most of his lifetime in the Senate.

And because of the people who will benefit from this bipartisan effort are the future Keilies, and thousands of patients who currently are not eligible for transplantation because they cannot afford the medication necessary after the transplant, we just simply have to keep pushing ahead.

Because of your efforts, they now have hope of receiving Federal funding for those drugs.

I hope this hearing continues that pattern—a pattern of cooperation and caring. I hope that during and after this hearing, we can continue to work together for new advances and new solutions to these problems; to work in that same spirit of caring and love for millions still so desperately in need of our help.

It is a tough area, a lot of tough questions; they are not easily answered, and some of them involve very difficult monetary and economic problems. But we will work them out, and we will just keep working on them, and we hope this hearing will take us well down that path today.

[Additional statement of Senator Hatch and the opening statement of Senator Grassley follow:]

Labor & Human Resources Committee
Senator Orrin Hatch, Chairman, Washington, DC 20510

June 11, 1986

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HATCH BILL WOULD REMOVE SOME OF THE FINANCIAL OBSTACLES TO ORGAN TRANSPLANTS

WASHINGTON -- New legislation has been introduced in the Senate by Sen. Orrin Hatch (R-UT) that would remove a major financial obstacle that restricts access to organ transplant surgery. The bill would authorize federal payment for immunosuppressive medications that are needed by transplant recipients who either lack health insurance or are under-insured.

Specifically, the Hatch proposal would amend federal Medicaid law by giving states the flexibility to add coverage for immunosuppressive drugs. However, the measure would not require states to extend this same treatment to an assortment of other services. It would also establish a three-year, $15 million annual grant to states for the immunosuppressive drug program.

Immunosuppressive drugs are vital to organ transplant recipients because they curb the body's immune system and prevent organ rejection. Use of these medications has been credited with the increase in the survival rates of transplant patients.

"Perhaps the most important drawback to the the use of immunosuppressants is their cost. These drugs which must be administered daily are expensive. In the first year of treatment, alone, the price can range anywhere from $5,000 to $7,000," Hatch said in remarks on the Senate Floor. "Can you imagine the heartache a family must feel when they are told that their loved one won't even be considered for a potentially life-saving operation because they don't have sufficient health insurance or enough money to pay for the surgery or post-operative medications," he asked?

Hatch told the story of Wayne and Rochelle Burrell of Roy, Utah who lived through that agony when they found out their little girl, Kielie, needed a liver transplant. Fortunately, their story had a happy ending because the Senator was able to get President Reagan to intercede on the Burrell's behalf. With the President's guarantee that Medicaid would pay some of the costs of Kielie's surgery, the University of Nebraska agreed to perform the operation.

He noted that some transplant recipients have been taken off immunosuppressants based on financial considerations as opposed to medical reasons, even though such action may cause the body to reject the donated organ. It is estimated that in 1985, 7,000 kidneys, 350 heart and 350 liver transplant operations were performed. Studies indicate that a successful kidney transplant represents a potential $30,000 to $60,000 savings to the federal government per patient over five years when compared to the cost of a life-time of dialysis.

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OPENING STATEMENT OF SENATOR GRASSLEY

Senator **Grassley**. Mr. Chairman, I am sure that this hearing today will help us take stock of the progress we have made over the last 2 years in improving our organ transplantation system. This is one of those areas in which we probably can make additional good progress in a relatively short time through the collaboration of State governments, private organizations and the Federal Government.

We have seen a draft of the report of the Task Force on Organ Transplantation and I think that our discussion of the issues related to organ transplantation will be advanced by it's work. Although there will probably not be agreement with the report on every point, it seems to me that those interested in improving the organ transplantation system and our policies on organ transplantation will be pleased to have the task force's extensive discussion and recommendations.

I am particularly pleased that the task force has taken account of the important part that State governments and private sector actors have, and must continue to have, in the operation of our organ transplantation system.

I am looking forward to the Department's response to the many proposals made for improvements in the transplantation system. I know that our committee will give serious consideration to the recommendations of the task force, and I hope will be able to act so as to continue the progress we have been making in this area in recent years.

That is all I have at this time, Mr. Chairman.

The **Chairman**. Senator Kennedy, let us turn to you.

OPENING STATEMENT OF SENATOR KENNEDY

Senator **Kennedy**. Thank you very much, Mr. Chairman, and I appreciate your kind and generous comments about our efforts in working together to fashion this legislation.

I would also like to commend the really splendid work of the Senator from Tennessee, Senator Gore, who both before coming to the Senate, in the House of Representatives, was working on this issue and has been a real leader on this question here in the Senate. I look forward to this testimony.

It has been almost 4 years since Charles Fiske, a Massachusetts hospital administrator, focused the attention of the Nation on the plight of American citizens who need organ transplants in order to survive and cannot find suitable donors. Mr. Fiske appealed to the national convention of the American Academy of Pediatrics for a liver to save the life of his dying daughter, Jamie. His impassioned plea was broadcast all over the country, and touched the hearts of Americans everywhere.

As media attention focused on the plight of other desperately ill children and adults, Americans began to be aware of the full scope of the organ transplant problem. While there are up to 26,000 potential donors every year, only 3,500 organs per year are actually procured. Because we lack an adequate national system to match donated organs with those needing transplants, a child in Massachusetts may die because his transplant team is not aware of an available organ in Texas. Thousands of people who need transplants each year either go without or suffer unnecessary organ rejection because they cannot afford the most effective immunosuppressive drugs. Some people are denied the surgery they need because they lack the ability to pay. A proliferation of organ transplant programs may result in unnecessary costs and lower quality of care.

In response to the clear need to improve our national procurement and transplantation policy, I and other members of Congress introduced legislation directed at aspects of this important problem. Hearings held by the Labor Committee on October 20, 1983, were followed by the enactment of the National Organ Transplantation Act of 1984, which was signed into law by President Reagan on October 19, 1984.

This legislation contained three key provisions: A mandate for the creation of a national organ matching and referral network, a program of grants to organ procurement agencies to establish more effective methods of increasing the supply of donated organs, and establishment of a 25-member Task Force on Organ Transplantation. The task force was charged with studying and reporting on all questions surrounding organ transplantation. It was specifically requested to examine the desirability of Federal support for the purchase of immunosuppressive drugs for transplant patients without insurance coverage.

The task force report is now complete and ready for publication. The distinguished members of the task force have endorsed all the key features of the National Organ Transplantation Act; they have strongly recommended a Federal program for the purchase of immunosuppressive drugs; and they have made a number of other recommendations for improvements in our Nation's ability to provide essential organ transplants to those who need them.

The report of the task force will provide welcome assistance in developing new legislation and initiating private action that will bring us closer to the goal of a fully effective organ procurement and distribution system.

But as important as these steps are, it is equally important that we implement the legislation already on the books. I am shocked at the fact that almost 2 years after the enactment of the National Organ Transplant Act of 1984, we still have no national organ matching network in place and we have not made a dollar of grant money available to any organ procurement agency to improve the supply of organs. Not only has the administration dragged its feet on implementing the new law, it actually proposed to rescind the money that Congress appropriated to fund the organ procurement agencies.

I am gratified that Congress rejected this rescission request. Just 3 weeks ago—19 months after the passage of the Organ Procurement Act—the administration finally published a notice of availability of the grant funds.

The tragic situation of children who need available organs in order to survive was emphasized again just a few weeks ago by the case of Alex Girard, a 9-month-old Massachusetts child who needed a liver transplant. Despite efforts by Alex's parents, my office, the news media, the transplant team at Boston Children's Hospital, and many others, a liver could not be located soon enough, and Alex died on the operating table.

I find it tragic that Alex might be alive today if the National Organ Transplantation Act had been promptly implemented.

Our hearing today will review the recommendations of the Organ Transplant Task Force and the administration's proposed response. Senator Hatch and I introduced legislation yesterday to implement one of the major task force recommendations—Federal funding for immunosuppressive drugs—and I intend to introduce additional legislation in the near future to respond to other recommendations of the task force.

I look forward to the comments of our distinguished witnesses on the legislation I and Senator Hatch have introduced and on the other recommendations of the task force. I am especially hopeful that the representatives of the administration here today will finally commit themselves to vigorous support and prompt implementation of the legislation already on the books and that they will support the essential new proposals identified by the task force.

I thank the Chair.

I also want to join in welcoming the Senator from Tennessee, who has been so helpful in providing leadership in this area, and I know we will gain from his comments and insights as to what in addition we ought to be doing here in the Congress.

The CHAIRMAN. Thank you, Senator Kennedy.

We are happy to welcome you, Senator Gore, to the committee as our first witness.

Senator Gore has been a leader in Congress in this area. I have enjoyed working with him and have had the pleasure of working with him when we passed the organ transplantation legislation in 1984 while he was a member of the House of Representatives.

I have no doubt that he is going to have an impact on whatever legislation comes through the U.S. Senate and through the Congress of the United States, and rightly so. He has earned that right, and he has my respect. Frankly, it has been my fault that we have not been closer together on this, and we will spend some time, just you and I together, on this legislation to see what can be done.

Welcome to the committee. We are glad to have you here.

STATEMENT OF HON. ALBERT GORE, JR., A U.S. SENATOR, FROM THE STATE OF TENNESSEE

Senator GORE. Mr. Chairman, Senator Kennedy, thank you very much, and thank you for your kind and generous words.

We have had a working partnership for several years, and I want to commend the two of you and this committee for the outstanding work that has been accomplished as a result of your efforts. When I was a Member of the House of Representatives, working on this legislation, it was always comforting to know that we had strong allies here who cared about the people we were trying to help and who were willing to really pitch in and work hard and immerse themselves in the details of this problem And it is a great pleasure to work with you, and I look forward to continuing that working relationship here.

I also want to commend you for having this hearing today, because we deserve to know why lives continue to be lost, and scarce health resources continue to be squandered 2 years after we passed legislation that was specifically designed to address this problem.

It is very frustrating in our constitutional system to have a situation where the Congress passes a law and the President signs that law, and then in spite of his oath of office to faithfully execute the laws, to have him refuse to do that, refuse to implement the law.

Now, that is exactly the situation we have here. The law was passed. It was signed by the President. Now, the administration fought tooth and nail against the National Organ Transplant Law, every step of the way, and it was only through the very hard work and delicate maneuvers of you, Chairman Hatch, and Chairman Waxman on the House side, and several of us working together, it was only through that work in the Congress that we were able to pass it over the objections of the administration.

Well, after it was passed, on October 19, 1984, President Reagan had a decision to make. He had opposed it; his administration had fought against it. Should he sign it? Should he veto it? Should he let it pass on without his veto? What would the decision be?

He decided to sign the law. For the prior 24 months since Charlie Fiske had taken to the airwaves to save the life of his daughter, Jamie, we had had a pitched battle. But on that day, October 19, the President had before him a comprehensive plan, a national plan, that had passed the House of Representatives by a vote of 396 to 6. It passed the Senate unanimously. Clearly, this was a measure with strong bipartisan support, nothing partisan about it.

So the President decided to sign the law, and in doing so, he pledged to the Congress and the Nation that he would faithfully carry out its instructions. And yet, what has happened? The President has not implemented the law. He has not kept his word in this respect.

This administration has spent the past 20 months still trying to get by without a national program, and still refusing to implement nearly every. single provision of the law. The cost to the country has been great. Countless families have suffered, and many lives have been lost.

To illustrate my point, I would like to submit for the record, Mr. Chairman, a recent New York Times editorial on transplant policy, entitled, "Putting Life on Hold." And in the words of this editorial, they say, "There ought to be a law—and there is." [1]

Well, this is the situation we face. We passed the law, and the administration refuses to implement it.

Now, in the 4 years since I began work on this issue, almost 4 years, not a single week has passed that my office has not received a plea for help. The names change. In the early years it was Jamie Fiske and Brandon Hall. Now, it is Baby Jesse, Jody Bell, John Faragi, and Alex Girard. But the desperate request is always the same. Family members come for help in finding donors, in getting surgery, and in ensuring access to essential immunosuppressive drug therapy.

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[1] The editorial referred to above is attached to Senator Gore's prepared statement.

Mr. Chairman, I know you share my frustration. I know you have received similar calls and have also worked very hard on this issue. But what do we tell families such as these? That they have to go on the Phil Donahue Show? Phil Donahue was instrumental in finding an organ for Baby Jesse. Is this the best we can do?

We distilled the best advice of the leading national experts and shaped it into a law and a national program and passed it overwhelmingly on a bipartisan basis. How do we explain to these families that Congress did address the issue, we did pass a law to help them, but that the President has decided to ignore it?

Now, Members of the House and Senate who served on the Conference Committee on this act were concerned about whether or not the administration would follow through and implement the law because it had fought against it so vigorously. We were particularly concerned that the administration would use a task force as a delaying tactic, refusing to go forward with other critical provisions of the law until a task force had had the opportunity to study them.

Well, now, the administration had ample opportunity to make the case for this approach in the Congress. It was debated on the House floor, and those who expressed the viewpoint of the administration offered it as an amendment. They offered an amendment that said wait a minute; let us have a task force and hold up any implementation of the provisions of this law until the task force has reported.

We had a clear, full-blown debate over exactly that proposition, and then we had a vote on it. The vote was 379 to 25. It is as if that vote did not take place now. And that was not changed in the conference, let me reiterate. The legislative history is clear and plain on this measure, with an overwhelming vote, and yet the administration has ignored the law and ignored the meaning of that vote.

Later, after a task force was added to specifically study the immunosuppressive drug question and questions of access to organ transplants, and the conferees included specific language in the conference report stating clearly that implementation of programs such as the Network and the grant programs should not be delayed pending the deliberations of the task force. It is clear. The law is clear. And the law has been ignored.

Congress carefully considered the administration's position, overwhelmingly rejected it, and made absolutely clear that all of the programs authorized by the National Organ Transplant Act should move forward concurrently.

Last year, the administration tried once more to undo the law. During consideration of the fiscal year 1985 supplemental appropriations bill, the administration slipped in language trying to accomplish its original goal. Let me read from it.

> Other programs authorized by the legislation such as the Organ Procurement and Transplantation Network and the Scientific Registry of Recipients of Organ Transplants cannot be implemented until the task force completes its work.

That is the language they tried to slip in the bill to do it again. We rejected it again. But still, they act as if the law does not exist.

Mr. Chairman, I really do not know what to make of this. Either the President has forgotten that he signed this law, or he feels his signature on the law has no meaning.

And if my words sound harsh in this respect, I intend it. I do not understand it. What do we do in a situation like this?

The administration's continuing contempt for the mandate of the American people on this issue is inexcusable. This attitude is evident again today in the refusal to provide this committee with Dr. Otis Bowen, the member of the President's Cabinet responsible for implementation of the transplant law, to answer the serious charges that have been raised.

Last month, the administration refused to send any representative to a House hearing on this same subject. Last week on the nationally televised show, "20/20", during a segment dealing with the effect of administration policy on transplant patients, the administration refused to answer any reporters' questions about this matter—in fact, ignoring the issue appears more and more to be the administration's transplant policy.

Now, the hardships that the administration has caused transplant patients and their families only began with its failure to implement the National Organ Transplant Act. Administration policy also left Anita Garner, the wife of a U.S. soldier, to die after she was denied a life-saving heart transplant because CHAMPUS refused to cover the procedure.

You may know why CHAMPUS refused to cover the procedure. It is because of the administration's policy that heart transplants are experimental.

Now, Mr. Chairman, as I have stated on other occasions, a pronouncement that heart transplants are experimental is a sham. It is an official lie. The best centers now have a 90-percent success rate. The overall national average, lumping the worst centers in with the good ones, is above 80 percent. How in God's name can that be labeled an experimental procedure? How can the U.S. Government tell the wife of an active-duty soldier that she has to die because we will not pay for an experiment that has a 90-percent chance of saving her life, because of official policy labeling it experimental? It is a sham. It should not be tolerated.

The abuse of the term experimental by the administration opens health care technology assessment to public ridicule. It has become a system too sensitive to political pressures and lacking any basis whatsoever in science.

Indeed, one of the most tragic aspects of Mrs. Garner's death is that had her husband, Robert, been a veteran whose health care was provided by the VA, her life could have been saved. For while one arm of the Government is calling heart transplants experimental, the VA has done over 100 heart transplants and considers the procedure routine.

The question of whether or not heart transplants are experimental was asked by Medicare 7 years ago On January 21, 1980, NIH answered the question, and I quote: "Cardiac transplantation should be accepted for Medicare reimbursement at those centers which demonstrate the expertise, resources, logistical plans and anticipated continuing concentration of experience necessary for high-quality results." I will supply this for the record—again, I do not want to clutter up your record, but if you care to have it, I will leave it up to you as to whether or not to include it.

The CHAIRMAN. We would be happy to have it.

Senator GORE. Instead of covering heart transplants, however, since that recommendation, Medicare asked for an extensive study—the National Heart Transplantation Study. That has been completed now. It was completed almost 2 years ago in September 1984. This extensive study strongly reinforced the previous conclusions that heart transplants are not experimental at all, that doctors and scientists do not have any disagreement whatsoever about this question. They are labeled a proven service.

And based on that study, in a memorandum dated October 19, 1985, 1 year to the day after the passage of this act, the Public Health Service and the Health Care Financing Administration again officially recommended Medicare coverage of heart transplants. The recommendation also stipulated that coverage be limited to designated centers. The memorandum proposes that coverage be limited to only those centers that have done at least 12 heart transplants per year for at least 2 years, demonstrating a 1-year survival rate of 73 percent and a 2-year survival rate of 68 percent. That is a tough policy, but it is one I support, and I hope the committee will support it at as well.

Well, 8 more months have passed since this extensive study and since the scientists and doctors spoke again, and we are still waiting for a coverage decision. I am told that in advance of this hearing, Mr. Chairman, there were several long meetings lasting into the night with people who know the score and who know the facts, urging upon the administration decisionmakers to come forward to this meeting here today and announce that they were going to do the right thing and accept the truth. But no, they were not able to do that.

In fact, today's hearing was rescheduled from May 21 to allow the administration additional time to get its act in order, to make the right decision. And yet today, after all this, the administration is going to come up here and tell you that the White House is still studying the question.

Frankly, Mr. Chairman, I am tired of watching them break the law. Is the White House really spending all this time debating the scientific facts of whether heart transplants are safe and effective? NIH stated in 1979 the procedure is unequivocally effective and safe. Or, is the administration saying while heart transplants are "safe and effective," they may not be reasonable and necessary?

Well, as you know, Mr. Chairman, the test for Medicare coverage is both safe and effective and reasonable and necessary. Over the years, there has been a great deal of debate about what is meant by reasonable and necessary, but the law is clear on this. It would take a change in the law to interpret reasonable and necessary any differently. I hope members of the committee will pursue this point with Dr. Roper and ask him what new elements beyond safety and efficacy the adminstration is introducing in stating that coverage of heart transplants is a policy question that requires further study.

The only legal question is whether or not they work. The administration is wrong to stretch the issue beyond safety and efficacy.

I know the committee, Mr. Chairman, is also very interested in the question of coverage of immunosuppressive drugs, and you referred to the legislation that you all introduced yesterday.

Quite simply, immunosuppressive drugs make transplants work. Without the drugs, a transplant patient's body is likely to reject the new organ. Unfortunately, however, immunosuppressive drugs are not cheap. Three years ago in hearings on the transplant issue in the House, my committee there found that many patients decide to pass up a transplant operation, even a kidney transplant, not because the operation is too expensive, since Medicare pays for it, but because they cannot afford the postoperative treatment. With Medicare refusing to pay for outpatient drugs, as many as 30 percent of those who need kidney transplants forego them. Others go through the operation and then must make do with ineffective substitutes for the most part for the more effective immunosuppressive drugs.

In fact, doctors often advise kidney patients who cannot afford immunosuppressive drugs not to have a transplant. These patients remain on dialysis because Medicare pays for it. We end up losing both in terms of the quality of life and in terms of dollars and cents, because the Government ends up spending far more on dialysis than it would to provide each patient the transplant and access to immunosuppressive drugs.

Yesteday, Mr. Chairman, I also introduced a bill on immunosuppressive drugs, and I would urge the committee to look carefully at the differences between the two measures that were introduced yesterday. And I would urge you also to ask the chairperson of the task force today, Dr. Olga Jonasson, who will be testifying later, to go over the task force's recommendations on this issue. The choice is between a block grant or an approach that has a national standard. And I will not belabor this point at this time, Mr. Chairman, because I look forward to discussing it in detail with you and other members of the committee. But let me just say briefly that the scientists and doctors and transplant organizations and the administration's own task force support the approach of having a national standard and not creating an extra layer through 50 separate State standards.

As I say, I do not want to belabor it at this time, but I certainly urge the committee to take a close look at the provisions involved here.

Now, in closing, Mr. Chairman, I do want to say that I am pleased you are going to be hearing from members of the task force, and I want to clarify one point here, and that is that although I am very frustrated that the administration has chosen to use the existence of a task force as an excuse for impeding action on this law, contrary to the intent of Congress and the meaning of the law, nevertheless, I believe that the members of the task force have done an excellent job, and many of their recommendations are of enormous value, especially in setting criteria for transplant centers.

So in closing, Mr Chairman, it is not too late for the President to carry out the promise he made to the American people in signing the National Organ Transplant Act 2 years ago.

What can we do to make him keep his word? How many desperate phone calls and deaths will it take? Could the President look

Paul and Ellen Girard, for example, in the eye and tell them that not having a national transplant policy was the best thing for their son? I think not.

Mr. Chairman, I know I have gone longer than is customary, and I genuinely am grateful for your indulgence and courtesy.

[The prepared statement of Senator Gore follows:]

STATEMENT OF THE
HONORABLE ALBERT GORE JR.
BEFORE THE
COMMITTEE ON LABOR AND HUMAN RESOURCES
11 JUNE 1986

MR. CHAIRMAN, I WANT TO COMMEND YOU AND AND THE OTHER MEMBERS OF THE LABOR COMMITTEE FOR CALLING TODAY'S HEARING TO REVISIT THE TRANSPLANT ISSUE. WE DESERVE TO KNOW WHY LIVES CONTINUE TO BE LOST AND SCARCE HEALTH RESOURCES SQUANDERED TWO YEARS AFTER THE CONGRESS AND THE AMERICAN PEOPLE DECIDED EXACTLY HOW THESE PROBLEMS WERE TO BE SOLVED.

DESPITE EVERY EFFORT ON THE PART OF THE CONGRESS TO CARRY OUT AN OVERWHELMING PUBLIC MANDATE TO ADDRESS THE SERIOUS MORAL, ETHICAL, AND LEGAL QUESTIONS RAISED BY THE REMARKABLE NEW TRANSPLANT TECHNOLOGIES, THE ADMINISTRATION'S STUBBORN AND BLATANT DISREGARD FOR THE LAW HAS LEFT MANY WONDERING WHAT IT WILL TAKE TO GET THE PRESIDENT TO DO HIS JOB.

MR. CHAIRMAN, TO ILLUSTRATE MY POINT, I WOULD LIKE TO INSERT IN THE RECORD A RECENT NEW YORK TIMES EDITORIAL ON TRANSPLANT POLICY ENTITLED "PUTTING LIFE ON HOLD." IN THE WORDS OF THE TIMES, "THERE OUGHT TO BE A LAW - AND THERE IS." THE REAL

TRAGEDY, SAID THE TIMES, IS THAT THE ADMINISTRATION HAS FAILED TO CARRY OUT THAT LAW.

ON OCTOBER 19, 1984, THE PRESIDENT HAD AN IMPORTANT DECISION TO MAKE. FOR THE PAST TWENTY-FOUR MONTHS, SINCE CHARLIE FISKE HAD TAKEN TO THE NATIONAL AIRWAVES IN A SUCCESSFUL EFFORT TO FIND HIS DYING DAUGHTER JAMIE A LIVER, THE REAGAN ADMINISTRATION HAD TRIED TO ARGUE THAT NO NATIONAL POLICY WAS NEEDED ON THIS ISSUE. IN FACT, THE ADMINISTRATION FOUGHT THE ENACTMENT OF THE NATIONAL ORGAN TRANSPLANT LAW EVERY STEP OF THE WAY.

BUT ON THAT DAY THE PRESIDENT HAD BEFORE HIM A COMPREHENSIVE NATIONAL PLAN. A PLAN THAT DESPITE HIS ADMINISTRATION'S STRONG OBJECTIONS HAD PASSED THE HOUSE BY A VOTE OF 396 TO 6, PASSED THE SENATE BY A UNANIMOUS VOTE, AND GARNERED THE STRONG BACKING OF THE AMERICAN PEOPLE AND EVERY MAJOR TRANSPLANT GROUP IN THE COUNTRY. THE PRESIDENT HAD A CHOICE. HE COULD STICK TO HIS POSITION AND VETO THE BILL, OR HE COULD SIGN IT INTO LAW.

THE PRESIDENT CHOSE TO SIGN THE NATIONAL ORGAN TRANSPLANT ACT INTO LAW AND IN DOING SO PLEDGED TO THE CONGRESS AND THE NATION THAT HE WOULD FAITHFULLY CARRY OUT ITS INSTRUCTIONS.

YET WHAT HAS HAPPENED? TRAGICALLY, THE PRESIDENT HAS NOT KEPT HIS WORD. HIS ADMINISTRATION HAS SPENT THE PAST TWENTY MONTHS STILL TRYING TO GET BY WITHOUT A NATIONAL PROGRAM AND

REFUSING TO IMPLEMENT NEARLY EVERY SINGLE PROVISION OF THE LAW. THE COST TO THE COUNTRY HAS BEEN GREAT. COUNTLESS FAMILIES HAVE SUFFERED AND MANY LIVES HAVE BEEN LOST.

A WEEK HAS NOT PASSED IN THE THREE AND A HALF YEARS SINCE I BEGAN WORK ON THIS ISSUE THAT MY OFFICE HAS NOT RECEIVED A PLEA FOR HELP. THE NAMES CHANGE - THREE AND A HALF YEARS AGO IT WAS BRANDON HALL AND JAMIE FISKE AND TODAY IT IS JODY BELL, JOHN FARAGI, ALEX GIRARD, AND BABY JESSE - BUT THE DESPERATE REQUEST IS ALWAYS THE SAME. FAMILY MEMBERS COME FOR HELP IN FINDING DONORS, GETTING SURGERY, AND INSURING ACCESS TO ESSENTIAL IMMUNOSUPPRESSIVE DRUG THERAPY.

MR. CHAIRMAN, I KNOW YOU SHARE MY FRUSTRATION. I KNOW YOU HAVE RECEIVED SIMILAR CALLS AND YOU HAVE ALSO WORKED HARD ON THIS ISSUE. WHAT DO WE TELL FAMILIES SUCH AS THESE? HOW DO WE EXPLAIN TO THEM THAT CONGRESS _DID_ ADDRESS THIS ISSUE AND PASSED A LAW TO HELP THEM, BUT THE PRESIDENT HAS DECIDED TO IGNORE IT?

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MEMBERS OF THE HOUSE AND SENATE WHO SERVED ON THE COMMITTEE OF CONFERENCE FOR THE NATIONAL ORGAN TRANSPLANT ACT WERE DEEPLY CONCERNED ABOUT WHETHER THE ADMINISTRATION WOULD IMPLEMENT A LAW IT HAD FOUGHT AGAINST EVERY STEP OF THE WAY. WE WERE PARTICULARLY CONCERNED THAT THE ADMINISTRATION WOULD USE A TASK

FORCE AS A DELAYING TACTIC - REFUSING TO GO FORWARD WITH OTHER CRITICAL PROVISIONS OF THE LAW UNTIL A TASK FORCE HAD THE OPPORTUNITY TO STUDY THEM.

THE ADMINISTRATION HAD AMPLE OPPORTUNITY TO MAKE ITS CASE FOR THIS APPROACH ON THE HOUSE FLOOR. THERE WAS COMPLETE AND THOROUGH DEBATE ON THIS VERY POINT. IN THE END, MEMBERS COULD CHOOSE - SHOULD TRANSPLANT POLICY AWAIT THE DELIBERATIONS OF A TASK FORCE? - AS THE ADMINISTRATION WANTED - OR SHOULD WE ACT IMMEDIATELY TO PUT A NATIONAL SYSTEM IN PLACE? THE ADMINISTRATION LOST BY A RESOUNDING 379 TO 25 VOTE.

LATER, AFTER A TASK FORCE WAS ADDED TO STUDY THE IMMUNOSUPPRESSIVE DRUG QUESTION AND QUESTIONS OF ACCESS TO ORGAN TRANSPLANTS, THE CONFEREES INCLUDED SPECIFIC LANGUAGE IN THE CONFERENCE REPORT STATING CLEARLY THAT IMPLEMENTATION OF PROGRAMS SUCH AS THE NETWORK AND THE GRANT PROGRAM SHOULD NOT BE DELAYED PENDING THE DELIBERATIONS OF THE TASK FORCE.

SO THE INTENT OF CONGRESS IS CLEAR. CONGRESS CAREFULLY CONSIDERED THE ADMINISTRATION'S POSITION, OVERWHELMINGLY REJECTED IT, AND MADE ABSOLUTELY CLEAR THAT ALL THE PROGRAMS AUTHORIZED BY THE NATIONAL ORGAN TRANSPLANT ACT SHOULD MOVE FORWARD CONCURRENTLY.

But the Administration simply continues to ignore the law. In fact last year it tried once more to undo it. During consideration of the FY85 supplemental appropriations bill, the Administration slipped in language trying to accomplish its original goal. Let me read from that bill: "Other programs authorized by the legislation, such as the organ procurement and transplantation network and the scientific registry of recipients of organ transplants, cannot be implemented until the task force completes its work."

Mr. Chairman, I don't know what to make of this. Either the President has forgotten that he signed this law, or he feels his signature on the law has no meaning. His Administration's continuing contempt for the mandate of the American people on this issue is inexcusable. This attitude is evident again today in the refusal to provide this committee with Dr. Otis Bowen, the member of the President's Cabinet responsible for implementation of the transplant law, to answer the serious charges that have been raised.

Last month, the Administration refused to send any representative to a House hearing on this same subject. Last week on the nationally televised show "20/20," during a segment dealing with the effect of Administration policy on transplant patients the Administration refused to answer a reporter's

QUESTIONS AS WELL. IN FACT, IGNORING THE ISSUE APPEARS MORE AND MORE TO BE THE ADMINISTRATION'S TRANSPLANT POLICY.

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THE HARDSHIPS THE ADMINISTRATION HAS CAUSED TRANSPLANT PATIENTS AND THEIR FAMILIES ONLY BEGIN WITH ITS FAILURE TO IMPLEMENT THE NATIONAL ORGAN TRANSPLANT ACT. ADMINISTRATION TRANSPLANT POLICY ALSO LEFT ANITA GARNER, THE WIFE OF A U.S. SOLDIER, TO DIE AFTER SHE WAS DENIED A LIFE-SAVING HEART TRANSPLANT BECAUSE CHAMPUS REFUSED TO COVER THE PROCEDURE, CITING MEDICARE'S POLICY THAT HEART TRANSPLANTS ARE STILL "EXPERIMENTAL."

AS I HAVE STATED OVER AND OVER AND OVER AGAIN, THAT PRONOUNCEMENT IS A SHAM. Most centers have a 90% success rate IT IS A LOUSY EXCUSE TO AVOID PAYING FOR A PROVEN SERVICE. IT IS AN EXCUSE THAT UNDERMINES PUBLIC UNDERSTANDING AND CONFIDENCE IN OUR ENTIRE HEALTH CARE TECHNOLOGY ASSESSMENT SYSTEM.

THE ABUSE OF THE TERM "EXPERIMENTAL" BY THIS ADMINISTRATION OPENS HEALTH CARE TECHNOLOGY ASSESSMENT TO PUBLIC RIDICULE. IT HAS BECOME A SYSTEM TOO SENSITIVE TO POLITICAL PRESSURES, AND LACKING ANY BASIS IN SCIENCE.

Indeed one of the most tragic aspects of Mrs. Garner's death is that had her husband Robert been a veteran whose health care was provided by the VA her life could have been saved. For while one arm of the government is calling heart transplants; "experimental" the VA has done over 100 heart transplants and considers the procedure routine.

The question of whether or not heart transplants are experimental was asked by Medicare seven years ago. On January 21, 1980 NIH answered, "Recommendations: #1. Cardiac transplantation should be accepted for Medicare reimbursement at those centers which demonstrate the expertise, resources, logistical plans and anticipated continuing concentration of experience necessary for high quality results."

Instead of covering heart transplants, however, Medicare asked for an extensive study - the National Heart Transplantation Study, which was completed in September, 1984. The study strongly reinforced the previous conclusions that heart transplants were indeed a proven service.

Based on that study, in a memorandum dated October 19, 1985, the Public Health Service and the Health Care Financing Administration again recommended Medicare coverage of heart transplants. The recommendation also stipulated that coverage be limited to designated centers. The memorandum proposes that

COVERAGE BE LIMITED TO ONLY THOSE MEDICAL CENTERS THAT HAVE DONE AT LEAST TWELVE HEART TRANSPLANTS PER YEAR FOR AT LEAST TWO YEARS. DURING THAT TIME THEY MUST DEMONSTRATE A ONE-YEAR SURVIVAL RATE OF 73 PERCENT, AND A TWO-YEAR SURVIVAL RATE OF 68 PERCENT.

THIS IS A TOUGH POLICY, BUT IT IS ONE I SUPPORT, AND I HOPE THE COMMITTEE WILL SUPPORT IT AS WELL.

EIGHT MORE MONTHS HAVE PASSED SINCE THAT RECOMMENDATION, HOWEVER, AND WE ARE STILL WAITING FOR A COVERAGE DECISION. A MONTH AGO, AT THE HOUSE HEARING, I DID ALL I COULD TO REMIND THE ADMINISTRATION THAT LIVES WERE BEING LOST AND THAT THEIR ANSWER WAS LONG OVERDUE. TODAY'S HEARING WAS RESCHEDULED FROM MAY 21ST UNTIL TODAY TO ALLOW THE ADMINISTRATION ADDITIONAL TIME SO THAT THEY COULD GIVE US THEIR ANSWER.

YET TODAY, AFTER ALL THIS, THE ADMINISTRATION IS GOING TO COME UP HERE AND TELL US THAT THE WHITE HOUSE IS STILL STUDYING THE QUESTION. FRANKLY, I AM TIRED OF WATCHING THEM BREAK THE LAW.

IS THE WHITE HOUSE REALLY SPENDING ALL THIS TIME DEBATING WHETHER HEART TRANSPLANTS ARE "SAFE AND EFFECTIVE?" - NIH STATED IN 1979: "THE PROCEDURE IS UNEQUIVOCALLY EFFECTIVE AND SAFE" - OR

IS THE ADMINISTRATION SAYING WHILE HEART TRANSPLANTS ARE "SAFE AND EFFECTIVE" THEY MAY NOT BE "REASONABLE AND NECESSARY?"

AS YOU KNOW MR. CHAIRMAN, THE TEST FOR MEDICARE COVERAGE IS BOTH "SAFE AND EFFECTIVE" AND "REASONABLE AND NECESSARY." OVER THE YEARS THERE HAS BEEN A GREAT DEAL OF DEBATE ABOUT WHAT IS MEANT BY "REASONABLE AND NECESSARY" - WHETHER OTHER FACTORS BEYOND SAFETY AND EFFICACY SHOULD BE CONSIDERED. BUT THE LAW IS QUITE CLEAR. HISTORICALLY, MEDICARE HAS ALWAYS SAID "REASONABLE AND NECESSARY" IS EQUIVALENT TO "SAFE AND EFFECTIVE." IT WOULD TAKE A CHANGE IN LAW TO INTERPRET "REASONABLE AND NECESSARY" ANY DIFFERENTLY.

I HOPE MEMBERS OF THE COMMITTEE WILL PURSUE THIS POINT WITH DR. ROPER AND ASK HIM WHAT NEW ELEMENTS BEYOND SAFETY AND EFFICACY THE ADMINISTRATION IS INTRODUCING IN STATING THAT COVERAGE OF HEART TRANSPLANTS IS A POLICY QUESTION THAT REQUIRES FURTHER STUDY. THE ONLY LEGAL QUESTION IS WHETHER HEART TRANSPLANTS WORK, AND THE ADMINISTRATION IS WRONG TO STRETCH THE ISSUE BEYOND SAFETY AND EFFICACY.

THE ADMINISTRATION CERTAINLY HAS THE RIGHT TO PUT FORWARD A NEW MEANING OF THE TERMS "REASONABLE AND NECESSARY," ONE THAT CONSIDERS COST, FOR EXAMPLE. THE COURTS HAVE MADE THAT RIGHT CLEAR. BUT THE COURTS HAVE ALSO MADE CRYSTAL CLEAR THAT AN

AGENCY CANNOT WILLY-NILLY APPLY DIFFERENT MEANINGS ON A CASE-BY-CASE BASIS. THE ADMINISTRATION MUST FORMALLY ANNOUNCE ITS NEW POLICY, AND APPLY IT NOT JUST TO ONE TECHNOLOGY BUT TO ALL COVERAGE DECISIONS.

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I KNOW THE COMMITTEE IS ALSO VERY INTERESTED IN THE QUESTION OF COVERAGE OF IMMUNOSUPPRESSIVE DRUGS. QUITE SIMPLY, IMMUNOSUPPRESSIVE DRUGS MAKE TRANSPLANTS WORK. WITHOUT THE DRUGS, A TRANSPLANT PATIENT'S BODY IS LIKELY TO REJECT A NEW ORGAN.

UNFORTUNATELY, IMMUNOSUPPRESSIVE DRUGS ARE NOT CHEAP. THREE YEARS AGO, IN HEARINGS ON THE TRANSPLANT ISSUE IN THE HOUSE, MY COMMITTEE FOUND THAT MANY PATIENTS PASS UP A KIDNEY TRANSPLANT NOT BECAUSE THE OPERATION IS TOO EXPENSIVE, SINCE MEDICARE PAYS FOR THE OPERATION, BUT BECAUSE THEY CANNOT AFFORD THE POST-OPERATIVE TREATMENT. WITH MEDICARE REFUSING TO PAY FOR OUTPATIENT DRUGS, AS MANY AS 30 PERCENT OF THOSE WHO NEED TRANSPLANTS FORGO THEM. OTHERS GO THROUGH THE OPERATION, THEN MUST MAKE DUE WITH INEFFECTIVE SUBSTITUTES FOR THE MOST MORE EFFECTIVE IMMUNOSUPPRESSIVE DRUGS.

IN FACT, DOCTORS OFTEN ADVISE KIDNEY PATIENTS WHO CANNOT AFFORD IMMUNOSUPPRESSIVE DRUGS NOT TO HAVE A TRANSPLANT. THESE

PATIENTS REMAIN ON DIALYSIS BECAUSE MEDICARE WILL PAY FOR IT. OVER TIME, THE GOVERNMENT ENDS UP SPENDING FAR MORE ON DIALYSIS THAN IT WOULD COST TO PROVIDE EACH PATIENT THE TRANSPLANT AND ACCESS TO IMMUNOSUPPRESSIVE DRUGS.

YESTERDAY, I INTRODUCED A BILL THAT WOULD REQUIRE THE GOVERNMENT TO PURCHASE IMMUNOSUPPRESSIVE DRUGS AND DISTRIBUTE THEM TO TRANSPLANT CENTERS AROUND THE COUNTRY THAT MEET MINIMUM STANDARDS TO ASSURE QUALITY OF CARE. THE HOUSE BACKED THIS APPROACH IN 1984, BY A VOTE OF 396 TO 6. IT HAD THE SUPPORT OF EVERY MAJOR TRANSPLANT GROUP IN THE COUNTRY. IT WAS LEFT OUT OF THE NATIONAL ORGAN TRANSPLANT ACT IN CONFERENCE ONLY BECAUSE THE ADMINISTRATION AND SENATE CONFEREES PROMISED TO ABIDE BY THE RECOMMENDATIONS OF A TRANSPLANT TASK FORCE. AFTER EXAMINING SEVERAL PROPOSALS, THE TASK FORCE ENDORSED OUR APPROACH LAST OCTOBER. WE ARE STILL WAITING FOR THE ADMINISTRATION TO KEEP ITS PROMISE.

ONE APPROACH SPECIFICALLY REJECTED BY THE TASK FORCE IS TO PROVIDE PATIENTS WITH IMMUNOSUPPRESSIVE DRUGS THROUGH A STATE BLOCK GRANT. MR. CHAIRMAN, I KNOW YOU ARE QUITE INTERESTED IN THIS APPROACH. I WOULD URGE THAT YOU ASK THE CHAIRPERSON OF THE TASK FORCE, DR. OLGA JONASSON, WHO WILL BE TESTIFYING LATER, TO GO OVER THE TASK FORCES'S RECOMMENDATIONS ON THIS ISSUE.

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Mr. Chairman, I don't want to take up any more of the committee's time this morning. You have already been quite generous in inviting me to testify.

I am pleased to see that you will be hearing from members of the Task Force on the findings and recommendations of their final report. Although I am disappointed that the Administration has used the Task Force as an excuse not to implement much of the transplant law, I believe many of the recommendations are of enormous value, especially in setting criteria for transplant centers.

Mr. Chairman, it is not too late for the President to carry out the promise he made to the American people in signing the National Organ Transplant Act two years ago. But what can we do to make him keep his word? How many desperate phone calls and deaths will it take? Could the President look Paul and Ellen Girard in the eye and tell them that not having a national transplant policy was the best thing for their son? I think not.

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Putting Life on Hold

Paul Girard of Sharon, Mass., recently begged for someone to donate a liver to save the life of his son, who needed a liver transplant. He called local newspapers, television stations and, eventually, the White House. When a liver was finally located and surgery performed, it was too late: Alex Girard died at the age of 9 months.

There ought to be a law to help avert such tragedies — and there is. The real tragedy is that Congress passed it two years ago but the Administration has resisted spending the $31 million appropriated to carry it out. Let it do so now, to avoid more Alex Girards.

The patchwork of organ retrieval programs around the country is linked by two private national networks — the North American Transplant Coordination Organization, in Pittsburgh, where Alex was listed, and the United Network for Organ Sharing, in Los Angeles. In 1984 Congress created a further linkage by providing the money to establish a nationwide computer bank to match organ donors and recipients.

It also set up a grant program that would encourage recruiting of potential donors. President Reagan signed the bill into law, but the money never arrived. Funding for the computer information clearinghouse was put on hold until a 25-member Organ Transplantation Task Force, set up to study the long-term issues associated with such surgery, finished its report.

To families like Alex Girard's, however, the long-term issues shrivel next to the need to save a child's life. The panel will release its report next month; some recommendations will provoke long debate. In the meantime, the computer network ought to be put into place — and to work.

The CHAIRMAN. We are happy to have you here, Senator Gore. I do not have any questions; do you, Senator Kennedy?

Senator KENNEDY. Just very briefly. In ensuring that we have the full record on the past actions or inactions by the administration, they never requested any appropriation, to implement the legislation, did they, Senator?

You remember for the improved procurement of various organs through grants to the organ procurement agencies part of that legislation would require that there be some appropriation in order to implement it. When the President signed that legislation, I think most families felt that he intended to implement it. And obviously, to implement it, there has to be some funding of the mechanism specified in the legislation for the improved procurement of those organs. The administration never requested it, and then when the Congress in its good judgment allocated a very small amount, $2.6 million, the administration actually gave us a rescission order, which was rejected; am I correct? Is that your understanding?

Senator GORE. It is absolutely right. They have requested nothing. They have issued a rescission order. They have fought against doing anything in this regard, with one exception. I might say for the record that they have requested $5 million for the U.S. Navy to conduct research and development on a bone marrow registry. There is an interesting story involved there that we can get into, if you like.

But as far as the National Organ Transplant Act, no, they have requested nothing, and they have fought against the initiatives of the Congress in this area to implement the law.

Senator KENNEDY. The Congress believed that within the HHS budget, there were existing resources to be able to develop the network for organ matching and dissemination, for that program, no separate appropriation by the Congress was required. That was our understanding at the time of the passage of the legislation. And yet, it took the administration some 15 months before an RFP actually was issued--15 months. No request for additional money. There was general understanding by the members of Congress and those who were involved in the legislation that there were existing resources to be able to do it, and then 15 months before it was actually implemented.

I think it is important, as we are going to have a continuing, ongoing pursuit of this whole issue, that we keep these points in mind.

I would just like to say that we appreciate your approach to the immunosuppressive drugs. We understand the difference. I think it is extremely worthwhile to hear the different alternatives, and we want to work with you on it.

Just very briefly, on some of the other recommendations of the work force—and I think it is important for the public to be aware of this recommendation—one of the suggestions is that when individuals go into the various hospitals that they at least have available to them the opportunity to be able to donate organs in the future. Many States provide on the back of their drivers' licenses people can indicate their desire donate their organs. But it is my understanding that this indication is not the final word, that hospital administrators believe that they have to have the next of kin approve to be able to actually move ahead with the procedure.

And one of the recommendations of the task force is that there is going to be available in the hospital and brought to the individuals who go to the various hospitals a routine request to allow them to indicate that they would want their organs to be permitted to be transferred.

Do you think that could be a useful informational technique that would be of value in terms of ensuring greater availability of organs in the future?

Senator GORE. Yes, but I think we cannot lose sight of the fact that the most important need is for a national system.

Senator KENNEDY. Exactly.

Senator GORE. But I agree with your earlier statement.

I did want to follow up on one other thing you said on the appropriations record. They also missed the December 15 deadline set in the law for coming forward on that. And the amount—and this is an important point—the amount that they have requested for the military R&D on a bone marrow registry is enough to implement the entire National Organ Transplant Act.

Senator KENNEDY. Well, I am leaving this hearing to go to a markup in Armed Services. Maybe we can find some means——

Senator GORE. I am not opposed to the other. It is just a question of priorities and so forth.

Senator KENNEDY. I understand. Finally, a couple of the other elements—one was the inclusion in the Medicare Program for heart and liver to be covered by Medicare. Would you support that?

Senator GORE. For heart and liver?

Senator KENNEDY. Yes, under Medicare.

Senator GORE. Oh, yes, absolutely. And let me tell you why that is particularly important. Because so many of the private insurance companies look at Medicare policy as the standard for their own policy. In some cases, there are antitrust questions involved, and there are other legal matters involved. So if Medicare comes forward and says, "This is U.S. Government policy," that is a signal for all of these other programs—CHAMPUS and private insurance companies, Blue Cross/Blue Shield, and the whole thing. And ironically, some of them just cannot stomach the Government's policy anymore, and they are going ahead without the Government—but not all.

And for the Government to say that a heart transplant is experimental is just plain wrong. I made that point earlier. But on liver transplants, let me tell you what they have done there.

They came in and announced at one of the hearings I held on the House side that they were going to make this big change in the law, and they were going to say that liver transplants were no longer experimental. But they put a hook in it. They said under Medicare, liver transplants will no longer be considered experimental for children under the age of 18 who suffer from biliary atresia.

Now, two points about that. Point No. 1, there is no basis for that distinction in medicine or science at all—none. Find a doctor who will support it. There is not one. I defy you.

Point No. 2, the practical effect of that condition is that the liver transplants are made available only for patients who are legally ineligible to receive them under Medicare.

So what do you make of that? In my view, it is just plain wrong, and I could use some stronger words, but I will not here.

I do not know what it is. I just hope that this committee can break it loose from the administration. And I would say to the chairman, if anybody on Capitol Hill can do it, you can do it. And I hope the administration will just get off this kick they are on. I do not understand why they are just refusing to do what the overwhelming majority of the American people want them to do, the overwhelming majority of Republicans and Democrats alike in the Congress. It is some hangup they have got. They just do not want the Government to have any new responsibility on their watch. That is my theory. If it is not that, I do not know what it is.

But I wish you the best of luck, Mr. Chairman, and hope to work with you and the other members of the committee in getting them to change.

The CHAIRMAN. Well, thank you, Senator.

Senator KENNEDY. If I could have one final comment, Mr. Chairman, kidney and liver have a different rate of acceptance in terms of the transplant success than, heart. One of the great medical centers—there are many—but one of the great medical centers in heart is out of Stanford, where Shumway has probably done as much in this area as anyone else.

Senator GORE. Right.

Senator KENNEDY. Now, what is the present life expectancy? Is it more than 5 or 5½ years.

Senator GORE. May I interject there? Bear in mind that that statistic was compiled before the introduction of the new immunosuppressive drugs, and the life expectancy is now expected to be much greater than that because they have the ability to control the greatest single medical problem that has given them such a battle.

Senator KENNEDY. Mr. Chairman, as you know, we have established a Bio-Ethics Committee which is bipartisan between the House and the Senate, and some of the very difficult and trying ethical issues and questions which you outlined in your opening statement, I would hope would absorb some of the time of that particular commission, because they are heart—rending situations, and the assistance and guidance bodies like this commission can give, can ease a lot of the anxiety and stress that many of these families feel at a very vulnerable period of time. And I would hope that this area of organ transplants might be an area that—I know Senator Gore is a member of that particular commission—and that we might be able to look at that.

The CHAIRMAN. Thank you, Senator Kennedy.

Senator Grassley.

Senator GRASSLEY. Mr Chairman, I have no questions, but I do want to put a statement in the record.

The CHAIRMAN. Without objection, we will do that.

Senator Dodd.

Senator DODD. Mr. Chairman, just very, very briefly—and I have no questions. But we rarely get an opportunity to have someone who really becomes an expert, a real expert, in the Congress, and

Al Gore, going back to our House days together, has really developed tremendous expertise in this area and deserves a tremendous amount of credit from people—regardless of one's political persuasion. We oftentimes say that to each other; it is sort of a public responsibility I think we feel. But in this particular instance, I could not be more sincere about it. You have done a remarkably good job on this issue, and you have built a strong base of support in this country and in the Congress on it; just keep at it.

Thank you.

Senator GORE. Thank you. I appreciate your kind words.

The CHAIRMAN. Thank you.

Senator NICKLES. Mr. Chairman, thank you very much.

I will echo the compliment to my friend and colleague, Senator Gore, and also to the chairman. I remember when we first had these hearings a few years ago, we got into the issue of organ transplantation and the need to increase public awareness, I hope that increased awareness is one of the outcomes of the hearing today. There is still a very serious, severe shortage of organs for transplantation throughout the country and we need to increase public awareness of it. We need to let more people know that the demand is there and that more lives can be saved if people would check their driver's license.

We can save lives and make substantial progress if we do that. The think the bill that we passed a couple of years ago was a step in the right direction.

I also want to compliment the task force, and I regret that I will not be able to be here for the rest of the hearing. I need to leave, because we are in a markup right now in another committee that I need to devote some attention to. But I compliment the task force. I have reviewed many of their recommendations, and I think they make some sense. I hope that we can get around this question of just strictly who is paying, whether it be Medicare or Medicaid, and private insurance. I'd like to encourage it to be done on the private side, and I hope we can fill some of the gaps that presently apply.

I personally have been involved in several fund-raising efforts where we try and help a family. It came to our attention that a 9-year-old girl and a 24-year-old mother were in need of heart-lung transplants. They received enough attention, and we got behind them, and a bunch of other people did, and we raised money for them. But the cost of that little operation was something like $250,000. And they had to raise $200,000 before they could even be admitted for services. And this is quite a drain and a very difficult thing, and in many cases, I am afraid, the families do not have the resources, or maybe they do not have the connection of knowing whom to contact to get the publicity to be able to mount the type of organized fundraising drives that are necessary to save their lives.

So I hope that if nothing else comes out of this hearing that again we will reacquaint people with the need, so they will become aware of the fact that there is still a shortage of donors, that we need more donors, more people willing to participate. And also I hope that we will be able to get around the roadblocks that have been raised concerning financing.

I compliment the chairman on his bill, and Senator Gore. I have not compared the bills. I was going to tell the chairman that I plan on cosponsoring your bill, and I do, or at least one or both of those bills. I think those are moves in the right direction, and hopefully, we will be able to make some positive moves toward helping to save some lives for those who are unfortunate enough to find themselves in these difficult circumstances.

The CHAIRMAN. Thank you, Senator.

Senator Simon.

Senator SIMON. I want to commend my colleague. I join Senator Dodd in saying it is good to see someone in the Senate—we are generalists, and we sometimes do not really get on top of anything. I am one who is not on top of this field like I would like to be. But it is great to see someone who is.

And I commend you, Mr. Chairman, for holding these hearings.

Senator Nickles mentioned a point that I could agree with. I pick up Illinois newspapers, and they are having a fund drive for somebody out there so they can survive. I think of the man in West Frankfurt, IL, a postal clerk. The only way his wife had the chance to live was with a liver transplant, but it was not covered by his insurance as a postal clerk. He got stuck with a $151,000 bill.

Somehow we have got to be able to put a couple of pennies on a package of cigarettes, or something. We should not have to go out, hat-in-hand, when somebody needs a liver transplant or a kidney transplant, or whatever it is. We ought to be able to solve this problem in this good society, and if all of us work at it, we ought to be able to do it.

The CHAIRMAN. Thank you, Senator Simon.

Al, I join with the others on your leadership in this area and what you have tried to do. I have to say, when we started the Kidney Dialysis Program, we figured it would cost tens of millions of dollars. This year, it cost us over $2 billion.

Now, nobody would say that it is not an important program, but nobody thought it would cost over $2 billion a year, and its cost is going up every year.

Organ transplantation has the same potential. That bothers me—I think we have to solve that; we have to face those cost problems squarely. I do not know whether the solution is adding 2 cents to a pack of cigarettes or whatever it is. But those are major problems. I suspect transplants have the potential of costing comparable amounts, if not more than the ESRD Program.

One thing that worries me about a Medicare solution, which was part of the task force recommendations, is paying for transplants from Medicare for the nonelderly. As you know, most elderly do not medically qualify for transplants. It seems to me you are taking money from the elderly, who themselves may not be medically eligible for transplants. So what about Medicaid; would that be more appropriate than Medicare?

I have wondered why they have come up with Medicare rather than Medicaid.

Senator GORE. Mr. Chairman, if I could respond to several things that you have just said——

The CHAIRMAN. Yes, go ahead.

Senator GORE. I think that the example of the ESRD Program may not be the correct example. You know, Mark Twain——

The CHAIRMAN. Well, it may not be, but——

Senator GORE. Can I finish the point, just briefly?

The CHAIRMAN. Yes, go ahead.

Senator GORE. Mark Twain said, "A cat burned on a stove will not sit on a hot stove again—but he will not sit on a cold one, either." And I think that there are differences between the two examples.

The task force itself points out, for example, that there are natural limitations to the number of transplants which can take place. There are only 20,000 brain deaths per year on average; with hearts, livers, heart-lung combinations, et cetera, that is the total number of potential donors each year. That is the first point. So you do not have an open-ended situation.

The second point—please bear in mind that there are large costs associated with allowing someone to die. We have preexisting ethical commitments in this country to providing comfort and care to people who are in the process of dying. And the expense associated with a lingering heart disease that requires long hospitalization can sometimes exceed the cost of a heart transplant, which makes it unnecessary.

In the case of kidney transplants, the cost of continued dialysis almost always exceeds the cost of the kidney transplant.

So, in many cases, what we are talking about is saving money as well as lives.

So, those two points, I think, are relevant.

Now, with specific regard to the task force recommendation, they recommended that Medicare cover it only for Medicare-eligible patients, as I understand it. Now, they recommended coverage for other patients without the ability to pay through a new program, not Medicare.

Now, you can ask the task force about this, but let me just briefly tell you the way I see the situation. The way I see it is transplants should be treated like any other medical procedure that is proven to be safe and effective.

The CHAIRMAN. But Medicare should only be used for Medicare-eligible people.

Senator GORE. That is correct—in my view, yes.

The CHAIRMAN. Yes, but as I understand it——

Senator GORE. And Medicare should be used, Medicaid should be used, CHAMPUS should be used, and private insurance policies should treat transplants just as they do any other procedure.

Now, if you make all of those decisions that I have just mentioned, you are still left with a group of Americans who are not covered under any of those plans, including private insurance. At that point, the argument for a special program to cover transplants for people who have no other kind of coverage is almost identical to the argument for catastrophic coverage of other kinds of diseases and conditions.

Now, the task force provides a new argument which is innovative, and I think it has some moral authority. They say that since we as a society ask for organ donations from rich and poor alike, therefore as a result, we have a special obligation to make the benefits of the procedure available to rich and poor alike. Now, that is an additional argument that we will all have to weigh. I think it has some force. But essentially, I think that people who are not covered under any of these other plans or programs should be covered through some kind of catastrophic health coverage that would deal not only with transplants, but with other conditions as well.

The CHAIRMAN. OK. I think those are wonderful statements, and I cannot disagree with any of them but there was a wonderful man over in the House, as you know, for many years who used to always stand up and ask the question: "Who is going to pay for this?" Medicare does not have unlimited funds; Medicaid does not have unlimited funds; we know CHAMPUS does not have unlimited funds; we know that the private industry is not going to voluntarily provide unlimited funds, and they do not have them, either. If we have to have catastrophic insurance that is another problem.

I think we have got to solve this problem. You know, today, our American technology is so sophisticated that literally, we have the capacity of extending almost anybody's life for a much longer time than we used to be able to do, and that ability is increasing every year. Sometimes, we have to take into consideration all of these problems. A lot of people feel that the Federal Government should not be the sole funding source, expending massive amounts of dollars to pay for transplants.

I will give you an illustration of the potential cost of these operations. It has been estimated that we could be performing between 1,000 and 1,400 heart transplants a year. That is over $1 billion right there, just in the one area of heart transplants. And that does not include the cost of followup care. I am not saying it should not be done. I think we have to find a way to do it. If it is the highest priority, we ought to find a way to do it.

On the other hand, we have got to answer the questions about where the bucks are going to come from. Keep in mind that just 2 years ago, we performed 33 percent fewer transplant operations than we are today. I suspect 2 years from now, it will go up another 50 percent, and I think that it will continue to expand.

Now, all I am asking is this—and I do not have the answer—but let us both work, and ask other colleagues as well, to start thinking about what is the answer: How do we solve this problem in the light of all of our our budgetary difficulties? How do we do it and do it in a responsible way so that it is morally and ethically fair for people across our society? Taking into consideration the needs of the taxpayers as well. Just help me on that. I do not need an answer today, because there is no easy, simple answer to it.

Senator GORE. Well, Mr. Chairman, I may be wrong, but I would like to suggest an answer, and that is to treat this procedure like other safe and effective procedures. There are many——

The CHAIRMAN. Well, even if, we do that, Al, it does not mean we have the money to pay for it. That is the problem.

Senator GORE. Well, first of all, remember that in your estimates, you have to subtract the amounts that are spent whether the transplant is given or not.

The CHAIRMAN. I agree.

Senator GORE. And if you look closely at those figures, you may very well find that the amounts of extra money involved are not all that large.

Second, how would you feel in telling a burn patient that there is a procedure that has a 90-percent chance of saving his life, but it is going to cost $100,000, and, "You are going to have to die because we decided"——

The CHAIRMAN. I do not think we have to do that. I think we have to solve those problems.

Senator GORE. But you see, that is what we are telling transplant patients today.

The CHAIRMAN. Sometimes that is true.

Senator GORE. But that is exactly what we are telling them. If you are a burn patient, your chances of survival may be less than if you need a heart transplant, and the cost may be more. But yet, because we are filled with compassion and filled with familiarity of the procedures involved, we say, of course, we are going to save this person's life.

Where the heart transplant patient is concerned we say, well, I do not know; this is new. You have a higher chance of living, and it is going to cost less, but this procedure was only discovered recently, so you have to die.

It is not rational. It is not fair. There are experimental cancer therapies that cost much more than transplants and have a miniscule chance of success, and yet we routinely fund them.

You see, I think the whole lifeboat approach to procedures of this kind is the wrong approach. I do not think we are at the stage where we have to start throwing patients out of the lifeboat to the sharks on the assumption that somebody has got to go.

Now, I will not belabor this point, but I think there is an ethical mandate to eliminate the wasteful expenditures and the practice variations that have been pointed out by a lot of specialists in this area, other examples of money that is just thrown down a rathole. I think we have got an ethical obligation to go ferociously after those funds in Medicare, Medicaid, private insurance, and elsewhere, before we start pitching people overboard on the assumption that we cannot save them, even though we know we could.

The CHAIRMAN. Yes, Senator Simon.

Senator SIMON. If I could just follow through, if we were to do precisely what you think we ought to do, what would the net cost be?

Senator GORE. Hold on 1 second here. [Conferring with staff.] To cover heart transplants under Medicare would be less than $10 million. Now, the leverage effect that would have on those private insurance companies that are not already covering them—and I think a majority already are—would have to be added to the Nation's total heart bill. But to the Government for heart transplants under Medicare, we are talking less than $10 million.

Senator SIMON. If we were to say for those covered by Medicare and not covered by Medicare, we are going to see to it that you are covered in this good, rich country that represents one-third of the world's economy—not only on heart transplants, but kidney, liver, the whole business—what would we be talking about? The chairman mentioned $1 billion.

Senator GORE. I will provide you a more precise estimate for the record, but basically, your methodology would be to take an average cost of the procedure—in this case for hearts, it would be $100,000—multiply it by the number of patients medically eligible for the procedure; in the event that went over the number of donors, you would have a total cap of $20,000 per year. It would not approach that in the early years, but that would be an overall cap. And then, you would subtract the amount of money that would be spent for terminal care, and you would add in the gain to productivity of the individuals whose lives were saved.

I will have to do those calculations and give you an exact—or an approximated—figure for the record, but I do not think it would approach the figures that were cited earlier. I will go through the calculations and try to buttress that statement.

The CHAIRMAN. Well, maybe I can help a little bit. We are presently spending about $400 million on transplantation in this country. Most people agree that that would at least double if we go to a system like Senator Gore is suggesting.

The Tell study indicated that there would be at least 1,000 to 1,400 heart transplants a year. My point is, if there is a way of doing it, let us do it; but let us also look at all the factors, let us make sure we do it right, and let us make sure we do it so it is not another blown-out-of-proportion program that is costing the taxpayers——

Senator GORE. Well, I do not disagree with that, but let us look at the factors on the other side, as well—the expensive terminal care, the gained productivity, and the like.

The CHAIRMAN. Sure. That is why we are holding hearings and that is why we are looking into it. But you know, I think we have to look at the reality, the stark reality, of what is it going to cost, and who is going to pay for it.

I think we can solve those problems. I think I have to bring pressure on the administration to get into the 21st century, and I certainly intend to do that. We have done that on a whole variety of health bills. And it is not the President; he always signs them. He loved the NIH bill, but he vetoed it, because that was the recommendation of OMB. And when he finally held the meeting in the White House on the new Muscolo-Skeletal and Arthritis Institute, he was very happy to do that.

So you have the two parts of Government and the administration fighting, at-odds, all the time, those who are saying, "Who is going to pay for this?" and those who say, "Well, our compassion says anybody should." And what we have got to do is bring the two together so the compassion comes through, but we also must treat the taxpayers fairly and everybody else fairly, those who are suffering as well as those who have to pay for it.

I appreciate what you have said here today because I think you have made a good case that we ought to do more in this area, and that is why we are holding this hearing, that is why we filed the immunosuppressive bill, and we are going to go from there.

Senator Simon.

Senator SIMON. Mr. Chairman, if I could just pull a figure out of the air that I am groping for in all this conversation, the net cost probably would not exceed $2 billion?

Senator GORE. Oh, I would think that would be a very high figure.

Senator SIMON. OK. That means that if we had an 8-cent tax on cigarettes—and maybe being from Tennessee, you would not favor that 8-cent tax on cigarettes, I do not know——

Sneator GORE. Maybe I would.

Senator SIMON. But whether it is that or some other means, we can——

The CHAIRMAN. Senator Gore, I am sure you can think of other things we can tax other than cigarettes, although Senator Simon and I are probably going to do that.

Senator GORE. Well, I might very well be willing to do that, but just go ahead with your example.

Senator SIMON. We are being asked by this administration to increase the military budget $31 million. Can't we squeeze a few bucks out here and there to do the kinds of things that are going to save lives? I think we can, if we really want to. I think the question is not one of resources; it is a question of will. And I commend you for your leadership.

Senator GORE. One final point on this. Even if we do not do that, there are some things that the administration could do this afternoon that would not cost a lot of money at all that would greatly facilitate the matching of donor organs with recipients, set up this national computerized registry, get the training and education programs underway in hospitals across the country—all for a total cost less than what they have requested for R&D in the military for one transplant program in the Navy.

The CHAIRMAN. Well, thank you, Senator Gore.

Senator GORE. You have been very generous with your time, Mr. Chairman.

The CHAIRMAN. Our next witnesses will be Dr. Ian MacDonald, ciate the expertise you bring with you.

Senator GORE. Thank you so much.

The CHAIRMAN. Our next witnesses will be Dr Ian MacDonald, Acting Assistant Secretary of Health, and Dr. Bill Roper, Administrator of the Health Care Financing Administration.

Dr. MacDonald and Dr. Roper will be representing the administration. As I understand it, the President is currently reviewing policy options in the area of organ transplantation and therefore, there are some areas of the administration's policies which they may not be in a position to discuss, but we will do the best we can here.

We are pleased to welcome both of you here this morning. We look forward to taking your testimony, and we will begin with you, Dr. MacDonald, first

STATEMENT OF DR. DONALD IAN MacDONALD, ACTING ASSISTANT SECRETARY FOR HEALTH, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC, AND DR. WILLIAM ROPER, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Dr. MACDONALD. Thank you, Senator.

Mr. Chairman, members of the committee, I am here today with Dr. William Roper, Administrator of the Health Care Financing Administration, HCFA, to discuss the Department's activities related to organ procurement and transplantations, the major recommendations of the Task Force on Organ Transplantation. I will discuss those issues related to the Public Health Service, such as organ procurement, donation, and sharing. Dr. Roper will address issues related to financing. Both of us will be available for questions at the completion of our statements.

A few months ago, I had the opportunity to participate in a special event within our Department to celebrate the gift of life—organ donation. The special event marked the start of National Organ and Tissue Donor Awareness Week, proclaimed by President Reagan to draw public attention to the need for donor organs. As part of the ceremony, I met three healthy children who had received the gift of life through successful liver transplants.

More people are receiving transplants than ever before, and more organs are being donated to make these transplants possible. It is this progress which makes even more pressing the need to be certain that high standards of quality are maintained to assure the best use of available organs for patients who are appropriate clinical candidates for transplant.

I would like to discuss some of the current activities in which we have been involved.

First, the Task Force on Organ Transplantation. After the passage of the National Organ Transplant Act in October of 1984, the Department moved rapidly to establish the task force. The task force was established in January, had its first meeting in February 1985, and during the 12 months that followed, the task force had public sessions on eight occasions and two public hearings. Work groups were established within the task force to prepare presentations and recommendations, and data was obtained through a variety of methods, individual task force members, literature reviews, and special studies, through consultation with experts in the field, and through public testimony.

Before I elaborate on the issues that apply to the PHS, I would like to observe how difficult it is to consider health issues like organ transplants in isolation from other significant health issues that compete for resources.

It should be noted that the task force was not asked to consider the problem of competing resources. It is the responsibility of policymakers, those of us who are stewards of the resources, to make such decisions.

RECOMMENDATIONS OF THE TASK FORCE

The Task Force on Organ Transplant has provided an important contribution to the national dialog on organ donation, procurement, and transplantation. The Secretary, Dr. Roper and I want to personally commend the entire group and publicly acknowledge the efforts of its chairperson, Dr. Olga Jonasson.

The task force will have provided two reports with 66 recommendations, the majority of which are directed to States, voluntary, private medical societies and associations. Fourteen of the recommendations are directed to the Federal Government.

ESTABLISHMENT OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

The task force was required by law to make recommendations for assuring equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and patients medically qualified for the procedures.

Equitable allocation of organs is one of the most important issues in organ transplantation and brings into focus the necessity for a system that is perceived by the public to be fair in distributing organs. Since this is one of the primary goals of a national organ-sharing system, we felt that we should not proceed with the establishment of this organ procurement network without recommendations of the task force. The task force's deliberations through the summer and early fall of 1985 led to the adoption of recommendations for a model network.

The task force recommended that the OPTN, which was mandated to be established by the act, establish uniform policies for organ procurement and transplantation that its membership would follow, and that it monitor participation of its membership in a national organ-sharing system.

The Department endorses the task force recommendations on the network. In doing so, we are encouraging the transplant community to better coordinate its activities. This will assure greater accountability and increase public trust.

The deliberations of the task force were subsequently used to develop specifications for a contract to establish the OPTN. The Congress appropriated $400,000 in fiscal year 1986 to establish the network. An announcement was published in the Commerce Business Daily, informing prospective bidders of the Department's interest in contracting for the establishment of the network.

Proposals were due on April 4, and the one proposal we received was found to be technically unacceptable. The bidder has been advised, and a new announcement was published May 23. New proposals are due July 28. We would expect that within this fiscal year, a network will be in place.

Once the network is established, it will be self-sufficient through membership dues, user fees, and other sources of revenue.

On the issue of organ donation, one of the most important issues addressed by the task force was the critical shortage of donor organs. All 50 States have adopted the Uniform Anatomical Gift Act, which gives us the right to donate any needed organs or tissues. Most States also provide people with an opportunity to sign up as a donor when they apply for or renew their drivers licenses.

In spite of this, the task force found that the public continues to have many fears and misperceptions about donation, and that while many potentially worthwhile efforts to conduct public education are underway in States and communities, gaps still exist because of lack of coordination.

The task force also found that families are often not informed of their option to donate organs and tissues after brain death is determined.

The task force recommended greater coordination and a nationwide educational program directed to families and underreached groups, including the development of more uniform information and statistics for the use of the many groups providing information.

The task force also recommended increased efforts to educate health professionals about donation, beginning in medical and nursing schools, to help overcome any reluctance to approach families of potential donors.

To enhance donation even further, the task force recommended several approaches for adoption of routine inquiry policies to assure that families of potential organ and tissue donors are routinely offered the opportunity to donate. These approaches include voluntary adoption of these policies by hospitals, as well as requiring hospitals to have such policies through State and Federal regulation.

Now that we have the task force recommendations, I think that there are ways the Department can help to increase organ donation.

First, we believe that many hospitals will want to adopt these policies on a voluntary basis, and we will actively work with groups such as the American Hospital Association and the Joint Commission on Accreditation of Hospitals to encourage this voluntary adoption.

Furthermore, we can assist in professional education through dissemination of information at professional meetings, and by serving as a catalyst to bring groups identified by the task force together to exchange information and assist them in developing educational programs.

Finally, we will continue to provide a focus of information on organ transplantation, and intend to initiate an active effort within the Office of Organ Transplantation to educate the public about organ donation

I believe that each of us and our families need to know what donation is all about. As a physician, I believe physicians, nurses, and other health professionals must take the lead in helping to spread the word about donation and talking about donation with patients and patients' families.

As part of our education, we need to learn that while donor cards are an important first step, just carrying one is not enough. Next-of-kin and other family members need to know of our wishes so they can carry them out. Families often say that donation brings a measure of solace at a time of great loss.

ORGAN PROCUREMENT

The task force reviewed the existing organ procurement system and found that there is a great variation in organ procurement agency performance, not only with respect to the number of organs procured, but also with those ultimately transplanted. In other words, some agencies have a large number of organs that they have procured, but are not transplanted, and others procure very few organs.

In addition, the task force found wide variations in cost for organ procurement among the agencies. To improve the overall effectiveness and reduce duplication of effort, the task force recommended that only one OPA be certified within a service area and that stronger certification and performance standards be developed. We intend to review reports of these Organ Procurement Agency activities to determine where deficiencies exist and identify those OPA's that may need technical assistance to achieve a greater degree of efficiency.

The task force has recommended that every organ procurement and transplant procedure be reported to the Organ Procurement and Transplantation Network, and unless centers comply, they would not be reimbursed by HCFA and other public payers for these procedures.

While we support the need for national data on organ transplantation, the Office of General Counsel has suggested that HCFA lacks the authority to deny payments for noncompliance.

EXCHANGE OF INFORMATION

The task force also recommended several ways to maintain the exchange of information and provide mechanisms to assure that the task force recommendations be implemented. We agree that widespread dissemination of information on organ transplantation benefits the field, but believe that current mechanisms are adequate to achieve this.

For example, information exchanges such as conferences and workshops sponsored by NIH is but one method. As the field of organ transplantation has evolved, the number of organizations representing the field has also increased, as have the number of medical journals where more current research is reported.

Also, there are existing data bases on liver, heart, kidney, heart-lung, and pancreas transplants. Medical scientists must continue to review the most appropriate ways to coordinate and share this information.

We believe that there is limited usefulness to general registries. At best, such registries include a variety of unique and unrelated data, and do not necessarily provide the relevant information required by researchers. Also, the tremendous rate of advancement in the field necessitates ongoing and revised data collection.

ESTABLISHMENT OF A GRANTS PROGRAM FOR ORGAN PROCUREMENT AGENCIES

The Organ Transplant Act established a grant program for qualified procurement agencies. Also required in the law was that the task force provide advice to the Secretary on how to implement this grant program. The task force recommended that an application for a grant be evaluated based on the applicant's ability to substantially increase the number of organ donors within a specified service area, and that priority also be given to applications for which no other sources of funding exist.

PHS has incorporated the task force recommendations into a "Notice of Availability of Funds" that was published on May 20. Applications are due by July 21. We received $2.6 million in fiscal year 1986 for this purpose, and we expect to make awards in September of this year.

Three types of grants will be available. One will be grants for planning and establishment of organ procurement agencies; another will be for the establishment and initial operation of these agencies, and a third for grants for expansion of current activities within existing agencies.

On the question of advisory board, the task force also recommended that a National Advisory Board on Organ Transplantation be established to monitor implementation of the task force recommendations and to serve in an advisory capacity to the Department. The Department believes such a group is not needed. The recommendations provided by the task force are clear and concise. My testimony before you today reveals our commitment to seriously consider all of the task force deliberations. As we consider these recommendations, we will of course be consulting with involved organizations and individuals.

The Office of Organ Transplantation established within the Health Resources and Services Administration will administer the contract for the network and for the Organ Procurement Agency Grant Program. It has also provided staff support to the task force and serves as our focal point for information on organ procurement and transplantation.

The office has coordinated the Department's participation in the National Organ and Tissue Donor Awareness Week for the last 2 years. Activities such as these are important in increasing awareness of the need for donors and the steps people can take to pledge donation.

In conclusion, Mr. Chairman, I would like to share some final thoughts about organ donation and transplantation. The greatest obstacle to saving lives among those who urgently need transplants is to increase the availability of donor organs. We need to inform and educate the public, and we need to enlist health professionals in this most important of tasks in order to, as President Reagan stated in his proclamation last month: "* * * make organ and tissue donation another expression of American generosity."

I will be glad to answer any questions you may have after Dr. Roper completes his statement.

The CHAIRMAN. Thank you so much.

[The prepared statement of Dr. MacDonald and response to question submitted to him follow:]

STATEMENT OF

DONALD IAN MACDONALD, M.D.

ACTING ASSISTANT SECRETARY FOR HEALTH

PUBLIC HEALTH SERVICE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

U.S. SENATE

JUNE 11, 1986

Mr. Chairman and Members of the Committee:

I am here today with Dr. William Roper, Administrator of the Health Care Financing Administration (HCFA) to discuss the Department's activities relating to organ procurement and transplantation. The major recommendations of the Task Force on Organ Transplantation. I will discuss those issues related to the Public Health Service (PHS) such as organ procurement, donation, and sharing. Dr. Roper will address issues related to financing. We will both be available to answer questions after completion of both statements.

A few months ago, I had the opportunity to participate in a special event within our Department to celebrate the gift of life--organ donation. The special event marked the start of National Organ and Tissue Donor Awareness Week, proclaimed by President Reagan to draw public attention to the need for donor organs. As part of the ceremony, I met three healthy children who had received the gift of life through successful liver transplants.

More people are receiving transplants than ever before, and more organs are being donated to make these transplants possible. It is this progress which makes even more pressing the need to be certain that high standards of quality are maintained to assure the best use of available organs for patients who are appropriate clinical candidates for transplantation.

And now I'll discuss some of the current activities in which we have been involved.

The Task Force on Organ Transplantation

After the National Organ Transplant Act was signed in October 1984, the Department moved rapidly to establish the Task Force on Organ Transplantation. The Task Force was established in January and met for the first time on February 11, 1985. During the 12 months following this organizational meeting, the Task Force met in public session on eight occasions and held two public meetings. Workgroups were established within the Task Force to address the mandated issues identified by Congress, and to prepare presentations and recommendations for consideration by the full membership. Data were obtained through surveys conducted by individual Task Force members, through literature reviews and special studies, through consultation with experts in the field, and through public testimony.

Before I elaborate on issues that apply to PHS, I would like to observe how difficult it is to consider health issues like organ transplantation in isolation from other significant health issues that compete for resources. It should be noted that the Task Force was not asked to consider the problem of competing resources. It is the responsibility of policymakers, those of us who are stewards of the resources, to make such decisions.

Recommendations of the Task Force on Organ Transplantation

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Establishment of an Organ Procurement and Transplantation Network

The Task Force was required by law to make recommendations for assuring equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and patients medically qualified for an organ transplant. Equitable allocation of organs is one of the most important issues in organ transplantation, and brings into focus the necessity for a system that is perceived by the public to be fair in distributing donor organs. Since this is one of the primary goals of a national organ sharing system, we felt that we should not proceed with establishment of the national Organ Procurement and Transplantation Network (OPTN) without the recommendations of the Task Force. The Task Force's deliberations through the summer and early fall of 1985 led to the adoption of recommendations for a model OPTN.

The Task Force recommended that the OPTN (mandated to be established by the National Organ Transplant Act) establish uniform policies for organ procurement and transplantation that its membership will follow, and that it monitor participation of its membership in a national organ sharing system. The

Department endorses the Task Force's recommendations on the Network. In doing so, we are encouraging the transplant community to better coordinate its activities. This will assure greater accountability and increase public trust.

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Organ Donation

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In spite of this, the Task Force found that the public continues to have many fears and misperceptions about donation and that while many potentially worthwhile efforts to conduct public education are underway in States and communities, gaps still exist because of lack of coordination. The Task Force also found that families are often not informed of their option to donate organs and tissues after brain death is determined.

The Task Force recommended greater coordination and a nationwide educational program directed to families and underreached groups, including development of more uniform information and statistics for the use of the many groups providing information. The Task Force also recommended increased efforts to educate health professionals about donation, beginning in medical and nursing schools, to help overcome any reluctance to approach families of potential donors. To enhance donation even further, the Task Force recommended several approaches for adoption of "routine inquiry" policies to assure that families of potential organ and tissue donors are routinely offered the opportunity to donate. These approaches include voluntary adoption of these policies by hospitals, as well as requiring hospitals to have such policies through State legislation or Federal regulation.

Now that we have the Task Force's recommendations, I think there are several ways that the Department can help to increase organ donation. First, we believe that many hospitals will want to adopt these policies on a voluntary basis, and we will actively work with groups such as the American Hospital Association and the Joint Commission for the Accreditation of Hospitals to encourage the voluntary adoption of these policies. Furthermore, we can assist in professional education through dissemination of information at professional meetings, and by serving as a catalyst to bring the groups identified by the Task Force together to exchange information and to assist them in developing educational programs. Finally, we will continue to provide a focus for information on organ transplantation, and intend to initiate an active effort within the Office of Organ Transplantation to educate the public about organ donation.

I believe that each of us and our families need to know what donation is all about. As a doctor, I believe physicians, nurses, and other health professionals must take the lead in helping to spread the word about donation and talking about donation with patients and patients' families. As part of our education, we need to learn that while donor cards are an important first step, just carrying one is not enough. Next-of-kin and other family members need to know our wishes so they can carry them out. Families often say that donation brings a measure of solace at the time of a loss.

Organ Procurement

The Task Force reviewed the existing organ procurement system and found that there is great variation in organ procurement agency (OPA) performance, not only with respect to the number of organs procured, but also those ultimately transplanted. In other words, some agencies have a large number of organs that are procured, but are not transplanted, and others procure very few organs. In addition, the Task Force found wide variations in cost for organ procurement among the agencies. To improve the overall effectiveness and reduce duplication of effort, the Task Force recommended that only one OPA be certified within a service area and that stronger certification and performance standards be developed. We intend to review reports of OPA activities to determine where deficiencies may exist and identify OPAs that may need technical assistance to achieve a greater degree of efficiency.

The Task Force has recommended that every organ procurement and transplant procedure be reported to the Organ Procurement and Transplantation Network, and unless centers comply, they would not be reimbursed by HCFA and other public payers for these procedures. While we support the need for national data on organ transplantation, the Office of General Counsel has advised that HCFA lacks the authority to deny payments for noncompliance.

Exchange of Information

The Task Force also recommended several ways to maintain the exchange of information and provide mechanisms to assure that the Task Force recommendations are implemented. We agree that widespread dissemination of information on organ transplantation benefits the field, but believe that current mechanisms to achieve this are adequate. For example, information exchanges such as conferences and workshops sponsored by the National Institutes of Health (NIH), is but one method. As the field of organ transplantation has evolved, the number of organizations representing the field has also increased, as have the number of medical journals where the most current research is reported. Also, there are existing data bases on liver, heart, kidney, heart-lung, and pancreas transplants. Medical scientists must continue to review the most appropriate ways to coordinate and share this information.

We believe that there is limited usefulness to general registries. At best, such registries include a variety of unique and unrelated data, and do not necessarily provide the relevant information required by researchers. Also, the tremendous rate of advancement in the field necessitates ongoing and revised data collection.

Establishment of a Grants Program for Organ Procurement Agencies

The Organ Transplant Act established a grant program for qualified organ procurement agencies. The law also required that the Task Force provide advice to the Secretary on implementing the grant program. The Task Force recommended that an application for a grant be evaluated based on the applicant's ability to substantially increase the number of organ donors within a specified service area, and that priority be given to applications for which no other sources of funding exist.

PHS has incorporated the Task Force recommendations into a "Notice of Availability of Funds" that was published in the Federal Register on May 20. Applications are due by July 21. We received $2.6 million in Fiscal Year 1986 for this purpose, and we expect to make awards in September of this year. Three types of grants will be available: grants for planning for the establishment of an organ procurement agencies, grants for establishment and initial operation of an organ procurement agency, and grants for expansion of current activities within an existing organ procurement agencies.

Advisory Board

The Task Force also recommended that a National Advisory Board on Organ Transplantation be established to monitor implementation of the Task Force's recommendations and serve in an advisory capacity to the Department. The Department believes that such a group is not needed. The recommendations provided by the Task Force are clear and concise. My testimony before you today reveals our commitment to seriously consider the Task Force deliberations. As we consider these recommendations, we will, of course, be consulting with involved organizations and individuals.

Office of Organ Transplantation

The Office of Organ Transplantation, established within the Health Resources and Services Administration, will administer the contract for the Network and the organ procurement agency grant program. It has also provided staff support to the Task Force and serves as a focal point for information on organ procurement and transplantation. The office has coordinated the Department's participation in National Organ and Tissue Donor Awareness Week for the last two years. Activities such as these are important in increasing general awareness of the need for donors and the steps people can take to pledge donation.

In conclusion, Mr. Chairman, I would like to share some final thoughts about organ donation and transplantation. The greatest obstacle to saving lives among those who urgently need transplants is to increase the availability of donor organs. We need to inform and educate the public, and we need to enlist health professionals in this most important of tasks, in order to, as President Reagan stated in his proclamation last month, "...make organ and tissue donation another expression of American generosity."

I will be glad to answer any questions that you may have after Dr. Roper completes his statement.

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DR. MacDONALD'S RESPONSE TO QUESTION BY SENATOR HATCH

Question: Last month, a particularly tragic episode occurred in Massachusetts when a baby died whose life might have spared had there been an adequate system for matching donor organs with people in need of a liver. Why has the Department not moved to develop a nationally based organ matching system?

Answer: While more effective mechanisms for matching donor organs to priority recipients are desirable, the real limitation is the difficulty in finding donor organs, particularly for small infants. The number of infants who die and whose organs are suitable for transplant is small. Matching is even more difficult than for adults because of the need to match organ size which is a much more critical factor in the small body of an infant. Further, in the case of the Gerrard baby, there were other complicating medical factors which made the search for a donor organ almost impossible. Tragic though these episodes may be, we must recognize that not every case of end-stage liver, or other organ, disease represents a good candidate for the potentially beneficial effects of transplantation.

The CHAIRMAN. Dr. Roper, we will turn to you now.

Dr. ROPER. Mr. Chairman, members of the committee, I would like this morning to follow Dr. MacDonald's statement by briefly discussing issues related to Medicare financing of organ transplants and related services.

A major issue that the Task Force on Organ Transplantation has addressed was the payment for organ transplant procedures and for immunosuppressive drugs used to prevent rejection of the organ.

Overall, the task force concluded that when public and private health benefit programs cover or pay for an organ transplant, they should cover outpatient immunosuppressive drugs to ensure a successful transplant.

The Department received the task force recommendations regarding immunosuppressive drugs in October of last year. The task force purposely limited its recommendation to kidney transplant recipients and called for the establishment of a HCFA-Public Health Service Program that would distribute immunosuppressive drugs to transplant centers free of charge for the neediest patients.

We have now had a chance to review this initial recommendation in the context of the task force's final recommendations regarding extra-renal transplant recipients. There are many public and private insurance programs that cover immunosuppressive drugs.

Beyond anecdotal reports, we find no evidence to indicate that the cost of immunosuppressive therapy has been a serious impediment to transplantation services to the American people. Moreover, we have concerns about institutionalizing a particular therapy or set of therapies when there are constantly emerging treatment that may prove to be more effective and less problematic than current immunosuppressive therapies.

Consequently, we could not support Medicare financing of immunosuppressive drugs, particularly under the approach advocated in the task force report.

Mr. Chairman, the coverage of organ transplants and related services is a difficult and sensitive issue. The human and financial costs of the illnesses requiring organ transplants is very great.

However, there are also Americans suffering from other catastrophic illnesses, and fairness to all members of our society dictates that their needs also be taken into account when the Government provides special financial assistance.

Therefore, the financial needs of those receiving transplants have to be considered as part of the broader issue of paying for the costs of catastrophic illness.

We have set out to do this. As you know, Secretary Bowen has been asked by the President to study a number of issues relating to the cost of catastrophic illness. This review is considering the issue of paying for immunosuppressive drugs and other costly drugs as well as the cost of transplant procedures themselves.

The task force recommended that private and public health benefit programs cover all transplants that are efficacious and cost-effective, and the task force considers heart and liver transplants to fall into this category.

The task force has also recommended that a public program be established to cover the cost of transplants for patients who have no other means to pay.

As you know, a great deal of interest has centered on Medicare coverage and payment for transplants. Coverage of transplants has long been the subject of study and deliberation within the Department.

Under statute, Medicare covers medical procedures that are "reasonable and necessary." The Department approved Medicare coverage for pediatric liver transplants in February 1984. The rationale for pediatric coverage derives from the demonstrative effectiveness of liver transplant in biliary atresia.

As a consequence of Medicare coverage, those State Medicaid agencies and other private insurers which follow Medicare coverage decisions are now paying for pediatric liver transplants.

Similar data and an experience base do not exist for adults where the range of etiologies leading to end-stage liver disease is much more considerable. For example, transplant experience of inpatients with malignant disorders involving the liver has been uniformly poor. The transplant experience with primary disorders of the liver, involving either toxins or viral parasitic or bacterial infections, has been highly variable, and data are insufficient at the present time to predict the probability of benefit.

For these reasons, Medicare continues to consider adult liver transplants as experimental and therefore, they do not meet the medical necessity criteria.

As you know, the issue of Medicare coverage of heart transplants has been the subject of study and deliberation within the Department for some time. We are now in the final stages of reviewing policy decisions on heart transplants, and we expect a decision shortly.

In conclusion, Mr. Chairman, we continue to assess the effectiveness of new technology which has potential for extending and improving the lives of Medicare beneficiaries. As organ transplant procedures become an effective and medically acceptable treatment modality, we need to decide how we can best make them available to transplant candidates. The task force report has provided valuable information to assist us in making these important decisions.

Thank you, and Dr. MacDonald and I are happy to respond.

The CHAIRMAN. Well, thank you.

Last month a particularly tragic episode occurred in Massachusetts, when a baby whose life might have been spared had there been an adequate system for matching donor organs with people in need of a liver.

Why has the Department not moved to develop a nationally-based system of matching organ donors with recipients?

Dr. MACDONALD. There are a lot of questions there, Senator. The business of establishing the network, I will get back to, but maybe to just review a little bit of the details of that unfortunate infant who died in Massachusetts.

To refresh the minds of some, I am a pediatrician who spent the greater portion of my productive life caring for kids in an office practice, and I have real easy ability to understand some of what must have gone on in that situation. But as best I can know it, this child in the latter part of the first year of life developed a progressive liver disease that was a very serious and rapidly moving process. When that infant was identified as having this process, an attempt was made to find a liver to fit, because in the opinion of his physician, nothing else would help.

The story is that it took a while to find a liver. It took 11 days. And I think that reflects not so much an inadequacy of the system, but the difficulty in finding livers of the right size in the right time period. The case that was in the paper today again demanded the death of a baby to give life to another one. So, what did happen was that 11 days later, an organ halfway across the country in Texas was found and transplantation was performed.

One of the things I would like to point out on baby liver transplants that I think is missed in this story also is that in the case of biliary atresia, which is a congenital abnormality of the liver, we have had very good success in terms of treatment with liver transplants, and indeed have recommended that that be considered safe.

In the business of hepatitis, whether we are talking about infant hepatitis or older hepatitis, the results are not as good. It seems as if the disease process continues in a high percentage of those livers.

So that what we are saying here is, I do not think the system failed; I think it is unfortunate that the infant had a very threatening condition, and we could not have done better, but with our present technology I do not think that if we had gotten the liver the same day that there is a whole lot of chance the result would have been any different.

The CHAIRMAN. I see. The task force and others have recommended expansion of the Health Care Financing Administration and its role in paying for organ transplantation, even though most of the transplantation patients are nonelderly.

Now, can you give us some idea of the impact this might have on the resources available for health care of the elderly, and wouldn't we run the risk of depleting really precious resources for them, which were primarily intended to help our elderly citizens pay for their own general health care if we go that route?

Dr. MACDONALD. I will defer that question to Dr. Roper.

The CHAIRMAN. Surely.

Dr. Roper.

Dr. ROPER. The Medicare Program, Senator, is set up, of course, to pay for the health expenses of the elderly and disabled, and we feel like it should not be expanded to a larger group, however important their health needs are. The Medicare Program has constrained resources, and we need to continue focusing on the beneficiaries of that program.

The CHAIRMAN. Well, Medicaid was established to help pay for the health needs of the poor, and for those who really cannot afford it. If we decide to expand Federal coverage for organ transplantation, wouldn't it be more logical to expand the Federal Government's role through Medicaid rather than Medicare under the circumstances?

I mean, it seems logical to me, but I hear this Medicare argument, and I just want to know the answer from your perspective.

Dr. ROPER. I would agree with you, Senator, and as you know, a number of States have already made the decision to cover liver transplantation, heart transplantation, through their Medicaid programs. States make the coverage decisions for Medicaid. Twenty-five States now cover heart transplants in their Medicaid programs.

The **Chairman**. I see. Now, the task force recommended Federal funding for immunosuppressive drugs, with the money to come from HCFA, and the program to be administered by the Public Health Service.

Could you, Dr. MacDonald or Dr. Roper, comment on the administration's approach to this?

Dr. **Roper**. I think the threshold question that Dr. MacDonald and I can respond to is should there be a new program financing immunosuppressive drugs. There still is a study underway of the general question of catastrophic illness costs, and Secretary Bowen will be coming forward with recommendations on that score later.

In addition, I have concerns about targeting resources particularly on a particular form of therapy when we are in an evolving period and a special program for immunosuppressive drugs may well freeze us in place with this particular therapy.

But finally, to your immediate question, I believe that Medicare funding should not be tapped into to pay for immunosuppressive drugs. Medicare does not cover outpatients' self-administered drugs, and I think that is an appropriate decision made years ago by the Congress.

Dr. **MacDonald**. The Public Health response to that would be that it really is a cost issue, I think, that we are talking about. If we were to administer or buy in large number, would we drive the cost down? I do not think there is any evidence to indicate that would happen.

We do presently buy vaccine, DPT for kids, as you know, and in a competitive market where there is more than one manufacturer, indeed we may get a better price in volume. I am not sure that would happen in a case such as cyclosporine, where there is one manufacturer.

There is no evidence that I know of that distribution channels are not adequate now. I think the only real question is the cost, and I do not see this one changing the cost at all, just adding an extra step.

The **Chairman**. Dr. MacDonald, can you comment specifically about the Public Health Service's concerns about being required to purchase the drug and then administer their distribution with regard to immunosuppressive drugs?

Dr. **MacDonald**. Well, I think the question is not unlike the previous one, where our position is that where medication is indicated as prescribed by the local physician, it is available and administered in dose as determined by them.

The question of where we would be involved, I really do not know. I think our involvement with immunosuppressives is really more in the area of when should you use them, what are the indications, how well do they work, rather than being a supplier.

The **Chairman**. Well, yesterday, we introduced legislation, of course, which would provide $15 million for immunosuppressive drugs to be administered by State governments. Would this approach be easier to administer, in your opinion?

Dr. MacDonald. Well, it would certainly be easier to administer from the Public Health Service standpoint. But again, I do not know how HCFA would feel about that.

The Chairman. How does HCFA feel about that, Dr. Roper?

Dr. Roper. Again, I return to the threshold question. We do not have evidence, other than anecdotal reports, that the lack of Federal funding for immunosuppressive drugs is keeping patients from being transplanted. I look forward to discussing your bill, but we are considering that basic issue.

The Chairman. I have other questions, but I may submit them in writing in the interest of time and turn to Senator Kennedy.

Senator Kennedy. I am actually rather appalled at that comment that you have no more than anecdotal information. I mean, I cannot believe that if you take any review of an average family's income that are involved in any of these programs and procedures, and find out the ability of these families to be able to pay—I think we are going to hear from a family later on during the course of the hearing—and if you draw the conclusion that it is anecdotal, I must say I am absolutely appalled at that kind of reasoning.

My son had cancer, and to get the chemical procedures it cost $2,700 a month. It was an experimental drug at the fine, so it was provided to the Children's Hospital up in Boston so families could get it without charge because it was basically funded by the NIH. Once the drug became accepted, it was $2,700 a month, and there were parents in there who were cutting that treatment off at 18 months and not going to 2 years. I could afford it, but they could not.

Dr. Roper. Senator——

Senator Kennedy. And if you do not think that this is not a prime problem and a prime concern, I say with all due respect to your area of inquiry that you are just not on top of it.

Dr. Roper. Well, you have eloquently pointed out the problem, Senator, and that is that there is a broader issue——

Senator Kennedy. I am talking just this issue here, now.

Dr. Roper [continuing]. Of the catastrophic costs of illness to all Americans.

Senator Kennedy. I am not getting away from that—I know about that, too. I have been working on that issue for 22 years, and I do not want to lose sight of that problem. I think these causes provide one of the strongest reasons for national health insurance that we will hear, ever.

You say we cannot do it under Medicare, because it is not set up that way. You want to go Medicaid. What are you going to do—bankrupt every family before they can get this kind of drug, because of the financial requirements and restrictions on the people who are eligible for Medicaid?

We have a reasonable amount of intelligence, and what you are telling us is the administration has not got a program to be able to deal with this problem, and the existing system is not going to work.

Well, that is not news to us here, and it certainly is not news to afflicted families. Part of the problem is that we do not have Dr. Bowen up here, who ought to be able to speak for the administration and ought to say what they are going to do and be able to respond to these questions. With all due respect, you have been sent up here trying to defend an indefensible position. And I admire your professionalism and commitment to public life, but it is an impossible position to put you in, and it is wrong, quite frankly; it is wrong for the administration to do that to you.

But I would hope you would not try to defend an indefensible position, and I would hope you would not suggest to us that there is not the kind of information available out there that would say that it is an intolerable situation for families that need transplants, and are not going to be able to afford drugs. To dismiss it and say it is just anecdotal is wrong.

Dr. ROPER. May I respond, Senator?

Senator KENNEDY. Sure, you bet.

Dr. ROPER. The point I am making is that, as you point out from your experience with your child with cancer, this is a broader issue than just immunosuppressive drugs and transplants. And we have in place at the President's direction a process focusing on the broader issue of catastrophic illness costs.

My point is that on the immediate question of immunosuppressive drugs and transplants, we do not have evidence that the lack of a Federal program to pay for those drugs is keeping people from being transplanted.

Senator KENNEDY. Well, I will just say, it is the typical old answer—we cannot solve all the problems, and therefore we are not even going to try and solve one of them. That is what I hear.

Dr. ROPER. We are working on it, Senator.

Senator KENNEDY. Others can draw their own conclusions, but that is what I hear.

We are focused on one area today. We will be focused on other problems at different things. We have got elderly people who cannot afford prescription drugs. I know all that rap. But we have got a particular issue here and a particular question. We might find out that if it works here, the American people might want it for others. That would be my judgment.

But to say we have not got the evidence or the information about the need for finding the cost of cyclosporine I find is, quite frankly, unacceptable.

Let me ask, Do you support the establishment of a national network?

Dr. MACDONALD. Yes, sir.

Senator KENNEDY. And can you tell us why it has taken the administration so long? The answer to that can be, "We just came to work on it," or whatever way you want to do it—or, if you want to try and defend it, go ahead and defend it.

Dr. MACDONALD. I am proud to try to defend it, or defend it.

Senator KENNEDY. OK.

Dr. MACDONALD. We support the importance of the network, and have. The question is how fast do you move in implementing a system in a field that is rapidly evolving and developing.

One of the provisions of the act that was passed in October 1984 was that we need to set up a network, but another provision was that we needed to set up a task force, and within their charge, they were given the charge of looking at the network. What we learned as the task force was bringing their recommendations in to us—and that was fairly rapidly done. In October 1984, the act; January 1985, the task force appointed; February 1985, the task force underway; late——

Senator KENNEDY. Just on this point, I do not want to lose the point. On the legislation of the Organ Transplant Procurement Act, page 15, the conference report, "The conferees do not intend the implementation of the grant program be delayed pending the deliberations of the Task Force on Organ Procurement." That is on the grant program.

I find it difficult, given Senator Gore and others who were here, how you could draw anything from the legislative history that would suggest that the Congress intended to delay the network until we got the task force report. We ran through all those arguments, as Senator Gore eloquently stated and testified to during the course of the morning, and to hear this old chestnut up here is, you know——

Dr. MACDONALD. I do not think the word was delay. I think the word was we tried to get it right the first time and felt that we did not have enough information or enough knowledge of where we are going in a very new field and wanted expertise to help us do that.

We learned a number of things from the task force——

Senator KENNEDY. Why do you have to wait for the task force? Why don't you just get your own advisory group and implement it—set deadlines, time limits, and do it?

Dr. MACDONALD. I think we could do that, but the same process of national public meetings, of scan, takes a period of time. You know, one of the things I learned as a physician is that it often is tempting to rush in, but many times, you wish you had gotten more data before you started.

Senator KENNEDY. Well, 15 months to even get the initial requests.

We have gone over—I think the record has been made. Nineteen months after the passage of the bill, there is still no network that is funded—19 months, 19 months.

Dr. MACDONALD. Let me point out one of the delays. One of the delays was that when we did advertise for a task force earlier this year, we only got one contract proposal that came back, and when we evaluated it—and there are five criteria on which we would evaluate this thing—it was found deficient in four.

Senator KENNEDY. We will have a chance, perhaps—I would love to have you submit to the committee how you went out soliciting for that report. I would love to find out. You only got one. I would love to find out. You only got one report; what was the outreach program? What did you really do down there to get it? I mean, I think that is shocking.

I would have welcomed the fact if you said that you did this, and you only got one report, and came up to Senator Hatch or me or the other members and said, "This is only what we have got, and it is not adequate to be able to do it, and we believe that there is an alternative way to try and get the job done."

But I mean, I want to see what the outreach program was to try and get it. I do not want to take a lot of the committee's time now.

Dr. MACDONALD. Let me just, if I may, respond quickly to that.

Senator KENNEDY. You bet.

Dr. MACDONALD. One is that there are two functioning networks in place now. And the other question, I think, goes back to the same thing. We are in a new field, and it is not to me particularly surprising that there were not a lot of people who came out and volunteered for something that did not have a lot said about it.

Senator KENNEDY. Well, the individuals who are calling Senator Gore's office and my own, and the families we have had come in desperate for an organ to save their dying child, are sure not aware of the two existing network systems. And we have mandated that you go ahead and do it. I think it is intolerable and unacceptable the time delay on it, and as I say, it is extremely difficult to understand the rationale within the administration on this.

Let me ask with regard to the procurement policy, can we finally get your commitment to implement the law and request the funding for the program?

Dr. MACDONALD. Yes, sir. We released a request for grant proposals on May 23. We expect that we will have more than adequate proposals come in and, if all goes well, fund those within this fiscal year.

Senator KENNEDY. Well, do I understand now that you will have a budget request for this in the next budget as well? Has the administration signed on, we are going to have a request, we are going to expend the resources?

Dr. MACDONALD. No, sir; I do not think that is in the next budget request. One of the things that we felt——

Senator KENNEDY. Well, why not? I mean, how can you say we are onboard now, and then you are not onboard for the next year?

Dr. MACDONALD. Well, we are onboard this year to develop proposals in the three areas that I mentioned, and our feeling is that these will become very quickly self-supporting, as will the network. The question is how long does the Federal Government subsidize something that is a profitmaking enterprise.

Senator KENNEDY. OK. Well, how about doing that subsidizing until you find out that it can work locally? How about putting the burden on the Federal Government and saying OK, we are going to fund it, and once you are able to spin this off in terms of local communities, then we will withdraw it, rather than saying we will do it for a year, and then we hope somehow it will be able to be funded, which it is not today, so we are going to terminate any kind of support.

The legislation does not say that. The legislation says you go out and fund it. And with all respect, Dr. MacDonald, quite frankly, we have made a judgment, and the President has signed it, and we are asking you to implement it. And to hear you say, well, we are going to fund it this year, and then we think something can happen out there, and then come back and repeal the legislation, or request that, or tell us about it.

Dr. ROPER. Senator, if I could just add a point. Under the Medicare Program, we are currently paying $100 million a year to organ procurement agencies. So it is not as if the Federal Government is not participating. That is in addition to the grant program that you are talking about.

Senator KENNEDY. Let us take the legislation. You tell me how much you are expending now, at the present time, under the legislation that was passed in 1984 and the particular provisions. Tell me that, Doctor.

Dr. Roper You all have already talked about that. That is the——

Senator KENNEDY. All right. That is what I am talking about. I do not want to get diverted. That is what I am talking about. I am delighted that the Navy is working in some of these areas. That is not what we are talking about. We are talking about this legislation, and that is not what is being implemented.

Have you formed any opinion about the number of medical facilities that ought to be able to go ahead with these procedures? Are you prepared to make a recommendation to us on that issue?

Dr. MACDONALD. Do you mean in terms of who should actually carry out the surgery?

Senator KENNEDY. Yes. I mean, we have the common problem, for example, in open heart surgery. We know there is enormous variation—I know there is in my State, and I know there is across the country—with the various successes and complications. And I think if we are going to get started in an important way in this, it is probably certainly worthwhile to review that particular policy question. The task force has a strong recommendation. I do not know whether you have got some reaction to it.

Dr. MACDONALD. Well, I guess the answer to that is that we are not prepared to make those recommendations today, but it is a very, very important question. When you talk about whether a procedure is safe, you have got to say under what circumstances, and certainly some of the circumstances you have got to consider are: Has anybody done it before in that area, what has been their track record, and a number of things.

We are looking seriously at concerns like credentialing, licensing, funding, but have not yet made a cut on which procedures we will or will not fund, and which place.

You have to understand that that is a major policy shift from the way we have treated American medicine in the past. We have not done this sort of thing with any other procedure I am aware of, and it is new territory—and important.

Senator KENNEDY. Yes. Well, I appreciate the fact that you are up here—you might not believe it, but I do appreciate the fact——

Dr. ROPER. Thank you, sir.

Senator KENNEDY. I think it is, quite frankly, an indictment of the administration. You are dedicated professionals; but you are trying to respond on the issues of policy and you are not free to speak your mind. We are entitled to have those that have responsibility for the program to come up here before the committee, with all respect. And I would hope that when you go back that you will indicate—at least, speaking for myself, and I imagine for others as well, that if this administration is going to be serious about it, they ought to send the people up who are the policymakers so that they can level with these families. Otherwise, we are failing, I think, to meet the responsibilities which all of us have.

I want to thank you very much.

I might have just some other technical questions which I would like to submit.

The CHAIRMAN. Thank you. We will keep the record open for questions from the committee on this.

Senator Pell.

Senator PELL. Thank you, Mr. Chairman.

I have two questions for you. The first is what is the status of organ transplants in other technologically advanced nations around the world. Could you just give us a brief overview of it. Are they more advanced than we, any nations, about the same?

Dr. MACDONALD. The status of organ transplants around the world, I would say you would have to say that the lead is in this country, as it is in much of American medicine. The technology, the science, came out of the Department of Health and Human Services, and we are the leaders.

Senator PELL. And this is not being done to the same extent in West Germany, the Soviet Union, Italy, and Britain?

Dr. MACDONALD. I do not know the numbers, but I suspect they will show that the majority of transplants have been done in this country—90 percent have been done in this country.

Senator PELL. And as we move ahead on the organ transplants, I know that the British, as a rule, I think, have a 50-year-old limit for kidney dialysis, for example, and above that you do not get it under their medical system; below that, you do. It is a question of expense.

Will it be our policy to have any arbitrary limits of that sort? Won't we probably have to have arbitrary limits from the viewpoint of expense?

Dr. MACDONALD. I suspect that it will not—and I will let Dr. Roper answer this—but when you are talking about transplant, you are talking about an additional thing. In renal dialysis, you are talking about controlling costs. One of the major problems in organ donation is availability of organs, so you run into that business, also.

Dr. ROPER. But Senator, the important question at hand is, is the person who needs an organ transplantation able to undergo the terribly complex and difficult medical procedure. So it is not simply a question of do they need an organ transplant, but rather, can they undergo it, and is it a safe and effective procedure in a person who may have other medical complications.

So I think that is important to bear in mind—not simply an arbitrary age cutoff, or whatever.

Senator PELL. Which would be a self-limiting factor, so that older people probably would not get the benefit of the organ transplant that a younger person would.

Dr. ROPER. Probably so; yes, sir.

Senator PELL. But it would not be a matter of regulation as it is in Great Britain?

Dr. ROPER. I think the physicians ought to be primarily the ones determining whether this is a patient that would be able to undergo a successful organ transplant, yes, sir.

Senator PELL. Thank you.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Pell.

We appreciate both of you coming. I hope that we can resolve some of these problems, and we look forward to your help and working with us through the coming months and years to be able to resolve some of the problems and, of course, do so in the best interest of everybody concerned.

Thank you so much. We appreciate having both of you here.

Dr. ROPER. Thank you, Senator.

Dr. MACDONALD. Thank you.

The CHAIRMAN. I might mention that we are really happy to have Ms. Linda Schaefer here as well. Linda is sitting right up in front. She has been the executive director for the task force, and I just want to compliment her for the hard work she has put in over the last couple of years on this issue. We just really appreciate it.

Our next witness is Dr. Olga Jonasson, chairperson of the Task Force on Organ Transplantation. Dr. Jonasson is also the chief of surgery at Cook County Hospital in Chicago.

Doctor, we welcome you to the committee. We thank you for joining us this morning, and we look forward to taking your testimony.

STATEMENT OF DR. OLGA JONASSON, CHAIRWOMAN, TASK FORCE ON ORGAN TRANSPLANTATION, AND PROFESSOR OF SURGERY, UNIVERSITY OF ILLINOIS DEPARTMENT OF SURGERY, COOK COUNTY HOSPITAL

Dr. JONASSON. Thank you, Senator Hatch.

Thank you for the privilege of being allowed to present the report of the task force which it has been my privilege to chair.

Our Report on Immunosuppressive Therapies was submitted to Congress in October 1985. Because most organ transplant recipients are unable to pay out of pocket for these expensive outpatient drugs, we recommend that by means of a grant from Medicare, the Public Health Service should purchase immunosuppressive drugs and make these drugs available to patients whose organ transplant procedures had been paid for by the Federal Government and had no other means by which to pay.

I would like to divert very briefly here to respond to some of the things that Dr. Roper said.

The task force specifically did not limit this recommendation to kidney transplant recipients. It recommended that all transplant procedures paid for by the Federal Government should be accompanied by a mechanism to obtain the immunosuppressive drugs. There is ample evidence that noncompliance with taking of immunosuppressive drugs is now the leading—or one of the leading—causes of late transplant failure.

We specifically did not specify a particular type of transplant therapy because this is an evolving field, but we felt that failure to provide these drugs was very unwise in terms of eventual costs.

We next examined the need to improve the supply of organ donors, now the critical limiting factor in expansion of kidney transplantation and liver transplantation for small children. And since the large majority of possible organ donors are never identified in the hospitals in which they are dying, we strongly recommend the enactment of legislation by all of the States, requiring that all acute care hospitals implement policies to routinely offer the next of kin the opportunity to donate organs and tissues.

We found a serious lack of uniformity and of standards of quality assurance and performance in organ procurement, and recommend that the Department of Health and Human Services set and maintain minimum performance and certification standards for organ procurement agencies and personnel.

We strongly urge that the development of an organ-sharing network proceed without delay and that funds be appropriated to implement the patient registry identified in the Organ Transplant Act.

Again, I will diverge to say that it is completely appropriate that only one response to the contract was received, since only one agency is capable of performing this task. Unfortunately, many technical flaws were discovered in the application.

Many of us fear that there will always be found to be technical flaws in this application and that this particular agency will never be given a contract.

Major financial barriers to liver and heart transplantation exist for many patients so that equitable access is effectively denied. We feel this is unfair and unjust. It is unfair to force patients in need of a life-saving transplant procedure for which the expected outcome is now very good to bear the entire burden of cost savings. If we must constrain costs, all patients should be asked to share the burden equally. It is unjust and is even a form of exploitation to ask all persons in this society, rich or poor, to donate organs and then allow only those who can pay for it to receive a transplant.

Therefore, we recommend that all transplant procedures that are efficacious and cost effective be made available to patients regardless of their ability to pay through existing public or private health insurance or, as a last resort, through a publicly funded program. Specifically, we recommend that Medicare pay for heart and liver transplants for eligible recipients.

We recommend the restriction of organ transplantation for nonimmigrant aliens to no more than 10 percent of kidney transplants in any center and recommend that heart and liver transplants be offered to nonimmigrant aliens only when no American resident is available as a recipient.

We are most concerned about proliferation of organ transplant centers in hospitals without proper staff experience or facilities. We fear several adverse consequences of this proliferation. In the absence of a proper environment, the results will not be good. The costs of unnecessary duplication of expensive staff and resources will be very high; and most serious of all, since the supply of organ donors is finite, every organ used in unqualified centers is an organ transplant denied to a recipient waiting in a qualified center where the outcome is likely to be better and where new and improved treatments are developed and available.

Therefore, we recommend that explicit criteria be used by the Department of Health and Human Services in designation of centers, and that only those centers which meet these criteria be eligible for reimbursement.

Finally, we recognize that the future of transplantation lies in research. We recommend strong support of both basic and clinical research in transplantation.

Thank you, Senator Hatch, I will be happy to answer any questions.

[The prepared statement of Dr. Jonasson, with attachment, follows:]

Statement of: Olga Jonasson, M.D.
Professor of Surgery, University of Illinois
Department of Surgery, Cook County Hospital

Senator Hatch, members of the committee:

Thank you for the opportunity to appear before you to present the report of the Organ Transplantation Task Force, which it has been my privilege to Chair.

As you know, the Task Force was established by the National Organ Transplant Act of 1984, and was convened by the Secretary of Health & Human Services in February 1985. Our membership included representatives from medicine and science, law, the health insurance industry, social and behaviorial sciences, organ procurement coordinators, and the public, including a dialysis patient. Representatives also attended from the Surgeon General, Food & Drug Administration, the National Institutes of Health, and the Health Care Financing Administration. We were ably assisted by the staff of the Office of Organ Transplantation, directed by Ms. Linda Sheaffer.

We met in formal public session nine times and on numerous occasions as small working groups, and addressed the issues identified by the Congress and by our members as being of greatest importance to transplantation today. I will briefly outline those issues in the order presented in our final report, and will highlight our conclusions and recommendations in each area.

We studied the modern generation of immunosuppressive medications used to deal with rejection of transplants, and submitted our report on this subject to Congress and the Secretary in October 1985. This report, which you have received, argues that the new immunosuppressive drug regimens, are a completely irreplaceable component of a transplantation procedure. Without long-term consistent immunosuppressive drug treatments, the transplant will fail in essentially all cases. It makes no sense to perform the expensive transplant procedure without making provision to assure that it will be successful. Although expensive, these drugs are eventually cost-saving due to substantial improvement in the outcome of transplantation and in reduction of hospital days. Using cyclosporine, many patients are able to be discharged in only a week following kidney transplantation, for instance, and are significantly less likely to experience failure of the transplant and to return to costly dialysis. Because most organ transplant recipients are unable to pay out-of-pocket for these expensive outpatient drugs, we recommend that by means of a grant from Medicare, the Public Health Service should purchase immunosuppressive drugs and make these drugs available to patients whose organ transplant procedure had been paid for by the Federal Government and who had no other means by which to pay.

Equitable access of patients to organ transplantation procedures will be facilitated by adoption of medical criteria as the sole basis for organ allocation. However, major financial barriers to liver and heart transplantation exist for many patients so that access is effectively denied. We feel this is unfair and unjust. It is unfair to force patients in need of a life-saving transplant procedure, for which the expected outcome is now very good, to bear the entire burden of cost-savings when other, equally expensive but much less successful, treatments are already paid for. If we must constrain costs, all patients should be asked to share the burden equally. It is unjust, and is even a form of exploitation, to ask all persons in this society, rich or poor, to donate organs and then allow only those who can pay for it, to receive a transplant. Therefore we recommend that all transplant procedures that are efficacious and cost-effective be made available to patients regardless of their ability to pay, through existing public or private health insurance or, as a last resort, through a publicly funded program.

We emphatically condemn the concept of commercialization of organ transplantation in which organs are bought and sold, whether this is in the context of cadaver or living donors. As a separate and very complex issue with humanitarian, ethical, and financial overtones, we have recommended the restriction of organ transplantation for non-immigrant aliens to no more than 10% of cadaver kidney transplants in any center and recommend that heart and liver transplantation be offered to non-immigrant aliens only when no American resident is available as a recipient.

We are most concerned about proliferation or organ transplant centers in hospitals without proper staff, experience, or facilities. We fear several adverse consequences of this proliferation: in the absence of a proper environment, the results will not be good; the costs of unnecessary duplication of expensive staff and resources will be very high; and, most serious of all, since the supply of organ donors is finite, every organ used in unqualified centers is an organ transplant denied to a recipient waiting in a qualified center where the outcome is likely to be better and where new and improved treatments are developed and available. Therefore, we recommend that explicit criteria be used in designation of centers and that only those centers which meet these criteria be eligible for reimbursement from any payer.

Finally, we recognized that the future of transplantation lies in research. We recommend strong support of both basic and clinical research in transplantation.

We next examined the need to improve the supply of organ donors, now the critical limiting factor in expansion of kidney transplantation and liver transplantation for small children. We recognize that public support for organ donation is very large but that gaps exist, and recommend improvements in public education, especially targeting minority populations in which the rate of donation is very low.

Also, since the large majority of possible organ donors are never identified in the hospitals in which they are dying, we strongly recommend the enactment of legislation by all the states, requiring that all acute-care hospitals implement policies to routinely offer the next-of-kin the opportunity to donate organs and tissues. We believe that such Routine Inquiry (Required Request) legislation would be the single most effective means of improving organ donation in this country. We also recommend adoption of the Uniform Determination of Death Act by all states.

We also found a serious lack of uniformity and of standards of quality assurance and performance in organ procurement and recommend that minimum performance and certification standards be set and maintained for organ procurement agencies and personnel, by the Department of Health and Human Services.

Although not part of our original mandate, the Task Force debated national organ sharing and concluded that the establishment of such a system could be a very effective means of assuring that organs are allocated fairly and equitably to patients and that maximal benefit would be obtained from each organ. At the request of the Office of Organ Transplantation we developed an outline of a Model National Organ Procurement and Transplantation Network which is built upon strong regional networks but which sets National policies for organ procurement and distribution. We strongly urge that the development of this network proceed without delay, and that funds be appropriated to implement the patient registry identified in the Organ Transplant Act for comprehensive collection and analysis of data for all organ transplantation activities.

ORGAN TRANSPLANTATION

Issues and Recommendations

DRAFT

EXECUTIVE SUMMARY

Report of the Task Force
on Organ Transplantation

April 1986

U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES
Public Health Service
Health Resources and Services Administration
Office of Organ Transplantation

DRAFT

EXECUTIVE SUMMARY

In response to widespread public interest and involvement in the field of organ transplantation, the Congress enacted the National Organ Transplant Act of 1984 (PL 98-507). In addition to prohibiting the purchase of organs, the act provided for the establishment of grants to organ procurement agencies (OPAs) and a national organ-sharing system. This act also established a twenty-five member Task Force on Organ Transplantation representing medicine, law, theology, ethics, allied health, the health insurance industry, and the general public. The Office of the Surgeon General of the Public Health Service, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Health Care Financing Administration (HCFA) were also represented.

The mandate given to the Task Force was to conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation and to report on these issues within one year. In addition, we were asked to assess immunosuppressive medications used to prevent rejection and to report on our findings within seven months; this report also was to include a series of recommendations, including recommending a means of assuring that individuals who need such medications can obtain them.

During the twelve months following its organizational meeting on February 11, 1985, the Task Force met in public session on nine occasions and held two public hearings. We were supported by staff from the Office of Organ Transplantation and by consultants from HFCA and other agencies and organizations. Data were obtained through surveys, literature reviews, commissioned studies, consultations, and public testimony. Five workgroups were established within the Task Force to address each of the mandated issues identified by Congress and to prepare presentations and recommendations for consideration by the full membership.

As required by the act, the Task Force completed an assessment of immunosuppressive medications and the costs of these therapies, and submitted its report and recommendations to the Secretary and the Congress on October 21, 1985. Briefly, we found that the new immunosuppressive regimens, although expensive, proved to be cost-saving due to improvement in outcome; for this reason, and in order to ensure equitable access, the Task Force recommended that the federal government establish a mechanism to provide immunosuppressive drugs to recipients otherwise unable to pay for these drugs, when Medicare paid for the transplantation procedure.

In this final report, the Task Force summarizes its arguments on the issues identified as major concerns by the Congress, and presents a series of recommendations for consideration of federal and state legislators, public health officials, the organ and tissue transplantation community, organized medicine, nursing, and the federal government.

ORGAN AND TISSUE DONATION AND PROCUREMENT

The serious gap between the need for organs and tissues and the supply of donors is common to all programs in organ transplantation, as well as to tissue banking and transplantation. The Task Force believes that substantial improvements in organ donation would ensue through new, innovative, and expanded programs in public and professional education and the coordination of efforts of the many organizations and agencies that engage in these activities. In particular, we support both the enactment of legislation in states that have not clarified determination of death based on irreversible cessation of brain function (the Uniform Determination of Death Act), and the enactment of legislation requiring implementation of routine hospital policies and procedures to provide the next-of-kin with the opportunity of donating organs and tissues. In addition, we found both a serious lack of uniform standards of accountability and quality assurance in organ and tissue procurement and a spectrum of effectiveness of procurement activities. Therefore, the Task

Force supports the development both of minimum performance and certification standards, and of monitoring mechanisms.

RECOMMENDATIONS

Facilitation of Organ Donation

1. The Task Force recommends:

- The Uniform Determination of Death Act be enacted by the legislatures of states that have not adopted this or a similar act.

- Each state medical association develop and adopt model hospital policies and protocols for the determination of death based upon irreversible cessation of brain function that will be available to guide hospitals in developing and implementing institutional policies and protocols concerning brain death.

- States enact legislation requiring coroners and medical examiners to give permission for organ and tissue procurement when families consent unless the surgical procedure would compromise medicolegal evidence. Further, the legislation should (1) require coroners and medical examiners to develop policies that facilitate the evaluation of all nonheart-beating cadavers under their jurisdiction for organ and tissue donation, and (2) provide the next-of-kin with the opportunity to consider postmortem tissue donation. The Task Force further recommends that coroners develop agreements with local tissue banks to help implement these policies.

Identification of Potential Donors and Routine Inquiry Policies

2. The Task Force recommends that:

o All health professionals involved in caring for potential organ and tissue donors voluntarily accept the responsibility for identifying these donors and for referring such donors to appropriate organ procurement organizations.

o Hospitals adopt routine inquiry/required request policies and procedures for identifying potential organ and tissue donors and for providing next-of-kin with appropriate opportunities for donation.

o The Joint Commission on the Accreditation of Hospitals develop a standard that requires all acute care hospitals to both have an affiliation with an organ procurement agency and have formal policies and procedures for identifying potential organ and tissue donors and for providing next-of-kin with appropriate opportunities for donation.

- o The Department of Defense and the Veterans Administration require their hospitals to have routine inquiry policies.

- o The Health Care Financing Administration incorporate into the Medicare conditions of participation for hospitals certified under subpart U of the Code of Federal Regulations, a condition that requires hospitals to have routine inquiry policies.

- o All state legislatures formulate, introduce, and enact routine inquiry legislation.

- o The Commission for Uniform State Laws develop model legislation that requires acute care hospitals to develop an affiliation with an organ procurement agency and to adopt routine inquiry policies and procedures.

Living Donors and the Donor Pool

3. The Task Force recommends that:

- o A study of the potential donor pool be conducted using data available through the National Hospital Discharge Survey, supplemented by regional retrospective hospital record reviews.

- Living donors be fully informed about the risks of kidney donation. Health care professionals must guarantee that the decision to donate is entirely voluntary. In the case of all living donors, special emphasis should be placed on histocompatibility.

- A national registry of human organ donors not be established.

Public Education

4. The Task Force recommends that:

- Educational efforts aimed at increasing organ donation among minority populations be developed and implemented, so that the donor population will come to more closely resemble the ethnic profile of the pool of potential recipients.

- At the regional level, single consortia, composed of public, private, and voluntary groups that have an interest in education on organ and tissue donation should develop, coordinate, and implement public and professional education to supplement, but not replace, activities undertaken by local programs.

- A single organization, such as the American Council on Transplantation, composed of public, private, and voluntary groups that are national in scope and have an interest in education for organ and tissue donation, should develop and coordinate broad scale public and professional educational programs and materials on the national level. This umbrella organization would both develop and distribute model educational materials for use by national and local organizations and plan, coordinate, and develop national efforts using nationwide electronic and print media.

- A national educational program should be established, similar to the High Blood Pressure Education Program of National Institutes of Health's National Heart, Lung, and Blood Institute, aimed at increasing organ donation. This program should include development both of curricula and instructional materials for use in primary and secondary schools throughout the nation, and of programs directed to special target populations, e.g., minority groups, family units, and churches.

Professional Education

5. The Task Force recommends that:

- Medical and nursing schools incorporate curricula focusing on organ and tissue procurement and transplantation.

- The Accreditation Council of Graduate Medical Education, the body responsible for accrediting residency programs, include requirements for exposure to organ and tissue donation and transplantation in relevant graduate medical education programs, such as emergency and critical care medicine and the neurological sciences.

- Each appropriate medical and nursing specialty board require demonstration of knowledge of organ and tissue donation and transplantation for board certification.

- All professional associations of physicians and nurses involved in caring for potential organ and tissue donors (especially neurosurgeons; trauma surgeons; emergency physicians; and critical care, emergency room, and trauma team nurses), establish programs to educate and encourage their members both to participate in the referral of donors and to cooperate in the organ donation process.

- Organizations of physician specialists who frequently come in contact with organ and tissue donors should establish mechanisms, such as a committee on transplantation, to facilitate communication and cooperation with physicians in the transplantation specialties.

Certification of Organ Procurement Agencies and Procurement Specialists

6. The Task Force recommends that:

- Professional peer group organizations, e.g., the North American Transplant Coordinators Organization, establish mechanisms for certification of nonphysician organ and tissue procurement specialists and standards for evaluation of performance at regular intervals.

- The Department of Health and Human Services certify no more than one Organ Procurement Agency in any standard metropolitan statistical area or existing organ donor referral area, whichever is larger.

- The Department of Health and Human Services use the criteria developed by the Association of Independent Organ Procurement Agencies as a guideline to develop consistent certification standards for Independent Organ Procurement Agencies and Hospital-Based Organ Procurement Agencies.

- The Department of Health and Human Services establish minimal performance productivity standards as part of a recertification process that could be conducted at regular intervals. Such standards should address procurement activity, organizational structure and programs, staff training and competence, and fiscal accountability.

o Appropriate peer organizations develop standards for certifying tissue banks and for conducting performance evaluations at regular intervals. Such standards should include assessment of quality and quantity of performance, organizational structure and programs, staff training and competency, and fiscal responsibility.

Responsibilities of Organ Procurement Agencies and Tissue Banks

7. The Task Force recommends that:

o The Department of Health and Human Services collect uniform data on organ procurement activities of all Organ Procurement Agencies, including, at a minimum, the number of kidneys procured, kidneys transplanted, kidneys procured but not transplanted, kidneys exported abroad, and relevant cost data. (The data could be collected through the Organ Procurement and Transplantation Network or from each Organ Procurement Agency.)

- The Department of Health and Human Services require all Organ Procurement Agencies to have, as a minimum, a form of governance that would be similar to that described for the national Organ Procurement and Transplantation Network, i.e., it should include adequate representation from each of the following categories: transplant surgeons from participating transplant centers, transplant physicians from participating transplant centers, histocompatibility experts from the affiliated histocompatibility laboratories, representatives of the Organ Procurement Agencies, and members of the general public. Representatives of the general public should have no direct or indirect professional affiliation with the transplant centers or the Organ Procurement Agency. Not more than 50 percent of the Board of Directors may be surgeons or physicians directly involved in transplantation, and at least 20 percent should be members of the general public. Where the governing boards of existing Organ Procurement Agencies differ from this composition, it is desirable that those boards be modified over a maximum to two years to achieve this distribution. The Task Force believes that all Organ Procurement Agency boards should consider immediate steps to include public representatives.

- Formal cooperative agreements be established among eye, skin, and bone banks.

- All Organ Procurement Agencies evaluate all potential donors for multiple organ and tissue donation.

- Organ procurement agencies and tissue banks enter into formal agreements for collaborative programs to educate the public and health professionals and to coordinate donor identifications, discussions with next-of-kin, and the procurement process.

ORGAN SHARING

The Task Force believes that establishment of a unified national system of organ sharing that encompasses a patient registry and coordinates organ allocation and distribution will go far in assuring equity and fairness in the allocation of organs. In addition, a national network organization, through adoption of agreed upon standards and policies, may serve as the vehicle both for improving matching of donors and recipients and for improving access of groups at special disadvantage (the sensitized and small pediatric recipients); thus, the outcome of organ transplantation in this country will surely improve. The development of a national network will permit the gathering and analysis of comprehensive data and, through the establishment of a scientific registry, will facilitate the exchange of new information vital to progress in the field. We assisted the

Office of Organ Transplantation in developing specifications for a model network, and urge that the National Organ Procurement and Transplantation Network be established promptly; in addition, we urge Congress to appropriate the funds necessary to initiate the development of the scientific registry.

RECOMMENDATIONS

1. **The Task Force recommends that:**

- **A single national system for organ sharing be established; that its participants agree on and adopt uniform policies and standards by which all will abide; and that its governance include a broad range of viewpoints, interests, and expertise, including the public.**

- **The national network establish a method to systematically collect and analyze data related to both kidney and extrarenal organ procurement and transplantation. Further, to provide an ongoing evaluation of the scientific and clinical status of organ transplantation, a scientific registry of the recipients of kidney and extrarenal organ transplants should be developed and administered through the national network, and the Task Force urges the Congress to appropriate funds to initiate this activity.**

2. The Task Force recommends that:

- Organ sharing be mandated for perfectly matched (HLA A, B, and DR) donor-recipient pairs and for donors and recipients with zero antigen mismatches (assuming that at least one antigen has been identified at each locus for both donor and recipient).

- A system of serum sharing and/or allocation of organs based on computer-determined prediction of a negative crossmatch, be developed to increase the rate of transplantation in the highly sensitized patient group by increasing the effective size of the donor pool.

- Blood group O organs be transplanted only into blood group O recipients.

- Because of the limited local and regional donor pools available to small pediatric patients, the national organ-sharing system should be designed to provide pediatric extrarenal transplant patients access to a national pool of pediatric donors.

- The national organ-sharing network, when established, should conduct ongoing reviews of organ procurement activities, particularly organ discard rates, and develop mechanisms to assist those agencies and programs with high discard rates. In the meantime, we recommend that the Department of Health and Human Services conduct a study to identify why procured kidneys are not transplanted and why the discard rates vary widely from one organ procurement program to another.

3. The Task Force recommends regional centralization of histocompatibility testing where it is geographically feasible, and standardization of key typing reagents and crossmatching techniques.

4. The Task Force recommends that the Congress appropriate funds to establish a national ESRD registry that would combine a renal transplant registry with a dialysis registry. The Task Force further recommends that the national organ-sharing network be represented on any committee responsible for management and data analysis of a national ESRD registry.

EQUITABLE ACCESS TO ORGAN TRANSPLANTATION

The process of selecting patients for transplantation, both in the formation of the waiting list and in the final selection for allocation of the organ, is generally fair and for the most part has succeeded in achieving equitable distribution of organs. However, the Task Force believes that these processes must be defined by each center and by the system as a whole, and that the standards for patient selection and organ allocation must be based solely on objective medical criteria that are applied fairly and are open to public examination. Moreover, as vital participants in the process, the public must be included in developing these standards and in implementing the policies. We recognized the complex conflict between need for an organ (medical urgency) and the probability of success of the transplant, and did not presume to make recommendations in this sphere; rather we believe that a thoughtful process of development of policies for organ allocation, which takes into account both medical utility and good stewardship, must take place within a broadly representative group.

The Task Force condemns commercialization of organ transplantation and the exploitation of living unrelated donors. The Task Force also addressed the difficult problem of offering organ transplantation to non-immigrant aliens. When transplantable organs are scarce, we have recommended that no more than 10 percent of all cadaveric kidney transplants in any center be performed in non-immigrant aliens and that extrarenal transplants be offered only when no suitable recipient who is a resident of this country can be found.* The Task Force also concluded that equitable access of patients to extrarenal organ transplantation is impeded unfairly by financial barriers, and recommends that all transplant procedures that are efficacious and cost effective be made available to patients, regardless of their ability to pay, through existing public and private health insurance or, as a last resort, through a publicly funded program for patients who are without insurance, Medicare, or Medicaid who could not otherwise afford to obtain the organ transplant.

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*See page ___ for a statement of exception from this recommendation.

RECOMMENDATIONS

1. The Task Force recommends that each donated organ be considered a national resource to be used for the public good; the public must participate in the decisions of how this resource can be used to best serve the public interest.

Information

2. The Task Force recommends that:

- Health professionals provide unbiased, timely, and accurate information to all patients who could possibly benefit from organ transplantation so that they can make informed choices about whether they want to be evaluated and placed on a waiting list.

- Information be published annually for patients and physicians on the graft and patient survival data by transplant center. A clear explanation of what the data represent should preface the presentation of data. A strong recommendation should be made in the publication that each patient discuss with his or her attending physician the circumstances of medical suitability for transplantation and where that patient may best be served.

Patient Selection

3. The Task Force recommends that selection of patients both for waiting lists and for allocation of organs be based on medical criteria that are publicly stated and fairly applied.

- The criteria for prioritization be developed by a broadly representative group that will take into account both need and probability of success. Selection of patients otherwise equally medically qualified should be based on length of time on the waiting list.

- Selection of patients for transplants not be subject to favoritism, discrimination on the basis of race or sex, or ability to pay.

- Organ-sharing programs that are designed to improve the probability of success be implemented in the interests of justice and the effective and efficient use of organs, and that the effect of mandated organ sharing be constantly assessed to identify and rectify imbalances that might reduce access of any group.

Non-Immigrant Aliens

4. The Task Force recommends that non-immigrant aliens not comprise more than 10 percent of the total number of kidney transplant recipients at each transplant center, until the Organ Procurement and Transplantation Network has had an opportunity to review the issue. In addition, extrarenal organs should not be offered for transplantation to a non-immigrant alien unless it has been determined that no other suitable recipient can be found.

Commercialization of Organ Transplantation

5. The Task Force recommends that as a condition of membership in the Organ Procurement Transplantation Network (OPTN), each transplant center be required to report every transplant or organ procurement procedure to the OPTN. Moreover, transplantation procedures should not be reimbursed under Medicare, Medicaid, CHAMPUS, and other public payers, unless the transplant center meets payment, organ-sharing, reporting, and other guidelines to be established by the OPTN or another agency administratively responsible for the development of such guidelines. Failure to

comply with these guidelines will require that the center show cause why it should not be excluded from further organ sharing through the OPTN.

6. The Task Force recommends that:

- Exportation and importation of donor organs be prohibited except when distribution is arranged or coordinated by the Organ Procurement and Transplantation Network and the organs are to be sent to recognized national networks. Even then, when an organ is to be exported from the United States, documentation must be available to demonstrate that all appropriate efforts have been made to locate a recipient in the United States and/or Canada. The Task Force has every expectation that these international organ sharing programs will be reciprocal.

- The practice of soliciting or advertising for non-immigrant aliens and performing a transplant for such patients, without regard to the waiting list, cease.

- Transplanting kidneys from living unrelated donors should be prohibited when financial gain rather than altruism is the motivating factor.

- To the extent federal law does not prohibit the intrastate sale of organs, states should prohibit the sale of organs from cadavers or living donors within their boundaries.

Payment for Extrarenal Transplantation

7. The Task Force recommends that private and public health benefit programs, including Medicare and Medicaid, should cover heart and liver transplants, including outpatient immunosuppressive therapy that is an essential part of post-transplant care.

o A public program should be set up to cover the costs of people who are medically eligible for organ transplants but who are not covered by private insurance, Medicare, or Medicaid and who are unable to obtain an organ transplant due to lack of funds.

DIFFUSION OF ORGAN TRANSPLANTATION TECHNOLOGY

The number of organ transplant centers in this country is rapidly increasing. As the technical aspects of the procedures have been mastered and patient management has become better understood and standardized, it is not surprising that diffusion of this technology has taken place. The issue of designating centers for reimbursement purposes requires careful consideration of many factors, including cost, criteria for facilities, resources, staffing, and the training and experience of personnel. After lengthy debate, the majority of the Task Force agreed with the widely accepted principle within surgery that the volume of surgical procedures performed is positively associated with outcomes and inversely related to cost and believe that this principle applies to organ transplantation procedures as well. Therefore, we recommend that a minimum volume criterion be enforced, together with other criteria defining the minimal requirements for both institutional and professional support and outcome of transplantation procedures. In the context of scarcity of donor organs, we strongly support regulating diffusion of transplantation technology.

Recommendations

1. **The Task Force recommends that transplant centers be designated by an explicit, formal process using well-defined, published criteria.**

2. **The Task Force recommends that the Department of Health and Human Services designate centers to perform kidney, heart, and liver transplants, and that the centers be evaluated against explicit criteria to ensure that only those institutions with requisite capabilities are allowed to perform the procedures.**

3. **The Task Force recommends that the Department of Health and**

Human Services adopt minimum criteria for kidney, heart, and liver transplant centers that address facility requirements, staff experience, training requirements, volume of transplants to be performed each year, and minimum patient and graft survival rates.

RESEARCH IN ORGAN TRANSPLANTATION

Organ transplantation continues to evolve and improve at a fast pace. Strong research programs in basic and applied clinical sciences have been vital to this fortunate development. As is clearly evident in the concerns of the public that resulted in the enactment of the National Organ Transplant Act, research also is needed in the social, ethical, economic, and legal aspects of organ donation and transplantation. The Task Force acknowledges the important role played by the NIH in transplantation research, and encourages the NIH to coordinate the free flow of information regarding transplant-related research through an interinstitutional council on transplantation. Moreover, we strongly urge that research on all aspects of transplantation be fostered and encouraged and that funding for this vital effort be increased. Therein lies the future of transplantation.

Recommendations

1. The Task Force recommends that basic research continue to receive high priority.

2. The Task Force recommends that both laboratory and clinical research of an applied nature directly related to transplantation also be fostered, encouraged, and increasingly funded. For the immediate benefit of patients, the Task Force further recommends that research be aggressively pursued in organ preservation and optimal immunosuppression techniques. The Task Force also wishes to emphasize the importance of sponsoring prospective clinical trials, involving multiple institutions, to solve certain problems in patient management.

3. The Task Force recommends that continuing attention be devoted to collecting complete information on the status and efficacy of transplantation treatments.

4. The Task Force recognizes that the interaction and exchange of information between the agencies involved in transplantation research and its funding must be encouraged. Therefore, we recommend that the National Institutes of Health be provided with resources to establish an interagency and interinstitute Council on Transplantation that will serve as a focus for this activity.

ESTABLISHMENT OF AN ADVISORY BOARD ON ORGAN TRANSPLANTATION

At the final meeting of the Task Force, where this report was adopted, a recommendation was made to establish a National Organ Transplantation Advisory Board. The Task Force agreed in concept that a national group to advise the Secretary of Health and Human Services would continue to be needed to monitor implementation of the Task Force's findings and serve in an advisory capacity on organ procurement and transplantation issues. Therefore we adopted the following recommendation:

The Task Force recommends that a National Organ Transplantation Advisory Board be authorised and funded to review, evaluate, and advise with regard to the implementation of the recommendations of the Task Force on Organ Transplantation, to serve in an advisory capacity to the Office of Organ Transplantation and to other transplant-related activities of the Department of Health and Human Services, and that this board be established in the Office of the Secretary.

A member of the Task Force distributed proposed model legislation to implement this particular recommendation. Because the Task Force did not have ample opportunity to review it from a substantive or legal standpoint, we agreed to append the proposal as it was received. (See Appendix A.) The inclusion of the proposal does not necessarily mean that the Task Force endorses this model or the mandate of the Advisory Board.

The CHAIRMAN. Well, thank you, Dr. Jonasson. I appreciate that, and I appreciate the excellent work that you have done. We really are appreciative of it.

There has been a lot of news coverage over the past week about Baby Jesse, a newborn who was denied a heart transplant initially because both of his parents were young and not married. The hospital reversed its decision, and, of course, this morning Baby Jesse received a heart transplant.

The task force looked at ways of setting criteria for transplantation. Do you think the criteria used in this case were acceptable? And, really, who should be setting the criteria for organ transplantation?

Dr. JONASSON. The criteria for selection of a patient for transplantation, we feel quite strongly, should be medical criteria; to apply other criteria such as social worth or wealth would be unfair and unjust.

We think that the responsibility for developing these medical criteria lies with the profession, but that certainly, the public should be involved in these overall policies. And since the public donates the organs and eventually pays for the procedure, we feel that the input of the public is extremely valuable in developing these policies.

The CHAIRMAN. Now, the task force recommended expanded reimbursement for transplant operations. Did the task force take into consideration what the cost would be, especially for followup care for patients, as well as the regular costs?

Dr. JONASSON. We did consider this fairly extensively, Senator—perhaps not the long-term followup care, but as has been pointed out, being extremely ill as all of these patients are is expensive in itself.

The costs as we have analyzed them for new costs from the Federal Government would be under $100 million for both heart and liver, for both Medicare and publicly funded programs for those who would be unable to pay for these procedures in any other way.

The CHAIRMAN. Now, the task force recommended an expanded role for HCFA and Medicare, it seemed to me, in paying for organ transplants.

Dr. JONASSON. Yes.

The CHAIRMAN. Did the task force consider the impact, including expanding Medicare coverage, that that migbt have on the elderly, since directly or indirectly, that money would have to come from their pockets one way or the other?

Dr. JONASSON. Yes. As I mentioned in my statement, we think that singling out the organ transplant recipients as the only patients in our society that are asked to bear the burden of cost savings is unfair to that patient population. And, as Senator Gore pointed out, the outcomes of organ transplantation are significantly better than many of the other, high technology procedures that are already being paid for. Rehabilitation of patients is the routine in organ transplantation, and the results are excellent. So we think it is very well-spent money.

The CHAIRMAN. Now, your task force did recommend funding for immunosuppressive drugs.

Dr. JONASSON. We did.

The CHAIRMAN. And we have introduced legislation which will provide the States with money earmarked specifically for that purpose. Now, do you think this legislation will satisfy the goals of the task force in that regard?

Dr. JONASSON. I must say I am very pessimistic, Senator, about that. We made the recommendation we did, that Medicare provide a grant to the Public Health Service in order to purchase these drugs for the following reasons.

First, we can document quite clearly that the new immunosuppressive drug regimen saves money in the long term. There is substantial reduction of failure, especially in kidney transplantation; dialysis is far more expensive than transplantation, so that the overall savings in the purchase of these drugs would be substantial, and the savings would accrue to the Medicare Trust Fund. We felt therefore that the Medicare Trust Fund should pay for the drugs, since they will realize the savings from them.

We also recommended that the drugs be purchased and given to patients through their transplant centers only if their were no other means with which to pay for these drugs. We felt that this was also extremely conservative an approach.

We specifically did not feel that block grants to States was an effective means, because of the extraordinary variation that States supply in awarding funds. We feel this is, frankly, quite unfair in many instances.

The CHAIRMAN. Dr. Jonasson, thank you. I am going to submit further questions to you and keep the record open so other members of the committee can do likewise. We appreciate your traveling here and being with us today. We know you have a busy schedule, and we know darned well how important you are, so we appreciate you being here and lending your weight to the discussion that we have had here today.

Dr. JONASSON. Thank you so much for having me.

The CHAIRMAN. Finally, I am especially pleased to introduce our last witnesses, Wayne and Rachelle Burrell from Roy, UT, the parents of a darling 1-year-old girl, Keilie. Keilie was born with biliary atresia and had to have a liver transplant last January to save her life.

Can you imagine the heartache a family has to feel when they are told that their loved one will not even be considered for a potentially lifesaving operation because they do not have sufficient health insurance or enough money to pay either for the operation or the postoperative procedures and medications? You can imagine how these folks felt, because they went through that.

So I am pleased for both of you that Keilie is doing so well. It was wonderful to see her when you were back here before. We just feel really happy to have you here today.

So we will turn to you, Mr. Burrell.

STATEMENT OF WAYNE AND RACHELLE BURRELL, ROY, UT, PARENTS WHOSE DAUGHTER HAS A TRANSPLANTED LIVER

Mr. BURRELL. Thank you, Senator Hatch.

We are honored to be here and have the once in a lifetime opportunity to testify at these Senate hearings today.

One year ago, June 20, our daughter was diagnosed with biliary atresia, a birth defect that affects the bile ducts in the liver. This defect seldom allows a child to live past the age of 3 years.

A Kasai procedure was performed in hopes of correcting the defect, but it was unsuccessful. The only option that was open at the time to save our daughter's life was a lifesaving liver transplant.

The medical expenses before the transplant were staggering, but then when we talked to our insurance company, they told us that they would not cover a liver transplant because it was considered experimental.

We started at that point to arrange for fundraisers in hopes of raising the needed money for the transplant. We needed $100,000 up front to guarantee Keilie a place on the transplant list.

With a persuasive letter from the transplant surgeons to our insurance company, they agreed to pay $50,000 of the total cost of the transplant.

In December 1985, Keilie's condition worsened, and our hopes of getting a liver became dim. On January 16, 1986, Keilie was put on the highest priority for a transplant, but we still needed $50,000 to insure the transplant.

On January 17, 1986, Senator Hatch's office was contacted. They in turn contacted President Reagan who insured the money to pay for the transplant. On January 18, 1986, Keilie went into a coma. A liver was found that afternoon, and Keilie was flown to the University of Nebraska Medical Center, where the transplant was performed.

Today Keilie is leading a normal life with an 85-percent chance of a long healthy life. When she reaches the 1-year mark of her transplant, she will have a 95-percent chance of living a normal life.

One obstacle that she will face the rest of her life is the cost of cyclosporine, an immunosuppressant. At this point, she goes through a bottle every 8 days, at the cost of $155 per bottle. At a cost of $620 a month just for cyclosporine, it makes it hard to afford basic necessities for the rest of our family.

Without financial help, I will have to drop my schooling and take on another full-time job just to pay for the cyclosporin.

With the cost of everything these days and all the money that needs to be appropriated for different areas, it is hard to decide where that money goes. And with Congress, in the blink of an eye, appropriating billions of dollars on ways to kill people, I think it will be a great day when the American people have the money they need to keep their children alive, and the Air Force has to hold a bake sale to buy a bomber.

That is all I have to say.

The CHAIRMAN. Well, I appreciate your testimony here today.

There is no question that this has been a tremendous experience in your lives to know your daughter is alive, and that she is alive because of an organ transplant. And I have to tell you that it has been a thrill for me and for our office to have participated with you. We have been able to do that in a number of instances, most of which have been successful, and a few of which have not been.

So as you can see, we are just tremendously happy for you. She is such a beautiful little girl, and I have to admit, I really became attached to her the 1 day we spent together. And we wish you the best.

Let me just ask you a couple of questions. Could you tell us a little bit about the support that you have received from your community and from your friends and others around you, both before and after Keilie's transplantation? Could you let us know a little bit about that?

Go ahead, Mrs. Burrell.

Mrs. **Burrell**. The support from our family and friends and people has been really great. We have had several fundraisers. In fact, Sunday, we just had a big fundraiser circus for Keilie's behalf. And people have been really wonderful to help us.

With Keilie's surgery and all, we were in for $120,000, and with us being a young family, we needed help from other people. And our families have been behind us 100 percent. They have helped support us in trying to get a liver, and they helped support us in trying to raise the money.

If it had not been for people, we would not have had enough money, and we are so grateful for people.

The **Chairman**. Yes, Mr. Burrell, go ahead.

Mr. **Burrell**. We have also had the help of the United Way, the March of Dimes, big organizations. We have had benefit concerts. It is hard to go out and solicit funds from people you do not even know. And in the year long that we have gone and solicited funds from people, we have not even come close to raising the amount of money to cover the initial cost of the transplant, let alone to try to afford cyclosporin after the operation. We pay more for cyclosporin in 1 month than we do for a house payment and a car payment, just to keep our daughter alive.

The **Chairman**. And you are a couple among a lot of people who have to do the same. And it is one of the things that we are trying to do with this bill we filed yesterday, and I think we will get that done.

I know that Keilie has had a tremendous effect on your family, the fact that she is now alive and healthy. Would you care to comment about that?

Mr. **Burrell**. She is a special child, not only to our family, but people all over the country, she has had an effect on them. Just the fact that she was in a coma, that it looked very dim for her, and that she made it through the operation and is leading a normal life right now, has given people a little bit of hope that liver transplants are effective. Now, with the percentage and the chance of living after one going up, it has given a lot of people a lot of hope, not only for my family, but a lot of families who are also waiting for transplants, and who are waiting for the livers to come in.

The **Chairman**. Well, you folks have given a lot of people a lot of hope by appearing here today, and we just want you to know that.

The questions that have been raised are very tough questions. They involve legalities, who gets the organs, what are the ethical questions involved, who is going to pay for the expense, how much is the expense going to be, is it going to run out of control, does it have to be taken from Medicare or Medicaid, or where; with limited resources, where do we find those funds.

The problems are almost insurmountable, but I assure you we are going to find some answers. We have got some answers. To some people, it is easy, just throw money at it, they will just go through it. They will never say, "Where do we get that money from?" Others do not do anything. I do not think there are many in the Congress in that category.

And then there are some who just plain have to be responsible and find out just what are all the answers to these questions, and that is what this task force is helping us to do to a degree. And we think it has come a long way to do that.

This committee has to act responsibly. This committee in part has been one of the reasons why we have $200 billion deficits. But over the last 5 years, as I have chaired this committee, it would be interesting to note, as liberal as it has been through the years, this committee without cutting one vital service, extending services actually to more people, bringing governance over the programs to the local areas, and making sure that the programs are not eaten up by bureaucracy, actually has effectively cut its budget 25 percent, its jurisdictional budget, while still doing all these things.

And if we can do that as one of the most liberal committees in the Congress, then I think the other committees can do as well. That translated means that if every other committee had done what this one has done, and reform the programs and make them work better and go farther and do more and reach more people, we would have a $150-billion surplus this year to be arguing over, and we would not be worried about what we do about organ transplantation. We would have the money there to do it.

So I think that is what we have got to do. It is always easy to say, "Let us throw money at this thing," but you have got to ultimately pay for that money one way or the other, the taxpayers, and so forth. But we are going to find that money; we have just got to do it. And I think we have got to set some priorities around here that are right, for a change, and I hope that we can do that.

And I assure you that the President feels exactly the same way. He has to deal with a massive bureaucracy here, and he has to deal with massive problems that are not very easy to deal with. And every time there is an expenditure here, he has got to at least hope for some way of saving elsewhere. And it is just an overwhelmingly difficult job, the most difficult job in the world.

So it is easy to criticize him, and it is easy to criticize others. I found myself in the prior administration—and I apologize for it—criticizing Jimmy Carter quite a bit for things, and I have learned since that, you know, it is a pretty tough job, and I think I was unjust in some ways in criticizing President Carter for some of the things that he was trying to do to save in government.

Well, I just want you to know how much I admire both of you. I think everybody on this committee does. And I think people all over the country will admire you for coming in and speaking out here today and letting people know how much this means to you personally, and that there are many, many others out there who need this type of help if we can but get it for them. So we are on our way, and let us just hope that we can find the answers to all these questions, and I will do my very best to do so, and I will do my very best to help the administration understand it as well—they do, but it is just a question of priorities and difficulties and constant shifting sands that are very difficult to deal with. It is always easy for us to say do this or do that about any particular project, but it is always difficult to implement that across the complete, countrywide budget that is very difficult under certain circumstances.

You people are very much respected by me, and I want you to know that, and I am just grateful to have you here from my home State as a sterling example of two people who have gone through it, who understand the pain of it, and who have a daughter alive because of help that you have been able to receive, both voluntary, governmental, and insurance help that really has all come together to help save Keilie's life. But most importantly, you folks have saved her life, and you deserve the credit, and we just want you to know that.

[Additional material supplied for the record follows:]

STATEMENT OF THE

HONORABLE GEORGE J. MITCHELL

before the

COMMITTEE ON LABOR AND HUMAN RESOURCES

JUNE 11, 1986

Mr. Chairman, I am pleased to have the opportunity to testify today on the subject of organ and tissue transplantation. I supported the National Organ Transplantation Act (PL 98-507) in 1984 and I commend you for holding this hearing to review its implementation and the recommendations of the Task Force on Organ Transplantation.

The Task Force made a number of very valuable recommendations in the areas of public and professional education, organ sharing, patient selection and payment assistance. I know that this committee will throughly review all of these concerns. As you well know, thousands more lives could be saved or enhanced by an improved organ and tissue transplantation system.

The recommendation which I will focus upon this morning is aimed at increasing the number of organ and tissue donors. Representatives of the Kidney Foundation of Maine came to see me in early April and told me of kidney dialysis patients in my state who have waited as long as 5 years for a transplant. Some have died. In response, I introduced the National Organ and Tissue Donor Act (S.2455) on May 15, 1986. Companion legislation has been introduced in the House of Representatives by Congressman Sam Gejdenson.

Nearly 20 states, including Maine, have taken action to increase the number of organs and tissues available for transplant, but the national initiative encompassed in S. 2455 is very much needed. More than 8,000 dialysis patients are waiting for a donor kidney, approximately 4,000 persons with impaired sight are waiting for corneas, and hundreds more are hoping that the organs or tissues they need will be available before it is too late for them. For each one who gets the chance of a new life through transplantation, many more die unable to wait any longer.

While cornea tissues may be retrieved from persons who have died of a variety of causes, hearts, livers, kidneys and other organs for transplant must come from young victims who have been declared brain dead but are maintained mechanically. There are approximately 20,000 such deaths each year, usually from auto accidents or cerebral hemorrhages, but last year only about 15% became organ donors. Whether or not these victims have signed donor cards, hospitals require the consent of a family member. However, in many cases the family is never given the opportunity to consider donation. Studies indicate that at least 70% of those asked will consent and that donation can be helpful to the grieving process. Knowing that other lives were saved is a source of consolation.

I am proud that Maine has acted to give life to those who wait and some consolation to those who grieve. But I am concerned that bills requiring routine inquiry procedures in hospitals have not even been introduced in about 20 states and have encountered opposition in a few others. I fear that unless more states act, the shortage will continue and some states may become net exporters of life-saving organs. Every state has a responsibility to participate.

In recognition of this responsibility, the National Organ and Tissue Donor Act directs the Secretary of Health and Human Services to encourage and assist states in enacting and implementing state routine inquiry laws. The bill sets minimum standards and requires the Secretary to report back to Congress in a year on the activities of the department and of the states. If state action is deemed insufficient, the Secretary shall recommend further federal initatives such as those sanctions suggested in the Task Force report.

I recognize that this bill is not a panacea. As the number of donations in routine inquiry states increases, efficient distribution will become even more critical. Alleviating the shortage would, however, make patient selection decisions easier and might well improve organ sharing arrangements. While I hope that your committee will put forth comprehensive legislation, I am very concerned that debate over the form that payment assistance should take not delay the drive for routine inquiry legislation.

Donation is not an easy topic, but it is of critical importance. Just in the last few years, medical science has made remarkable progress in improving matching techniques and preventing rejection of transplants. But the ability to save lives is severely impeded by the shortage of human organs and tissues. I sincerely hope that this Committee will shortly report legislation to the floor that will make routine inquiry national policy.

Thank you for allowing me to come before you to comment on one of the important matters before you this morning. Again, I commend you for holding this hearing and I look forward to reviewing the proposals which you and Senator Gore have made for providing assistance to transplant patients and their families in meeting the high cost of immunosuppressive drugs.

The CHAIRMAN. With that, we will recess this hearing until further notice.

Thank you so much.

[Whereupon, at 12:23 p.m., the committee was adjourned.]

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